IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. APOTEX INC., and APOTEX CORP., Defendants.	C.A. No.: 07-809-JJF-LPS **REDACTED VERSION DI 40**

DECLARATION OF DANA K. HAMMOND IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT APOTEX INC.'S RULE 12(b)(2) MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION, OR IN THE ALTERNATIVE TO TRANSFER TO THE MIDDLE DISTRICT OF FLORIDA

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Attorneys for Plaintiffs

I, Dana K. Hammond, declare:

1. I am an attorney at the law firm of Connolly Bove Lodge & Hutz LLP in Wilmington, Delaware and one of the counsel for Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha. I make this declaration based on my personal knowledge and the inspection of the documents attached hereto.

2. A true and correct copy of the "Paragraph IV" certification letter regarding the U.S. Patent No. RE 37,314 sent by Apotex Inc. to AstraZeneca, dated December 4, 2007, is attached hereto as Exhibit 1.

3. A true and correct copy of pages from AstraZeneca's Internet website, including the homepage, is attached hereto as Exhibit 2.

4. A true and correct copy of pages from Apotex Inc.'s and Apotex Corp.'s Internet websites, including the homepages, is attached hereto as Exhibit 3.

5. A true and correct copy of pages produced by Apotex Corp. in this litigation is attached hereto as Exhibit 4 (designated Highly Confidential by Apotex Corp.).

6. A true and correct copy of Apotex Inc.'s responses to AstraZeneca's interrogatories in this litigation, dated April 2, 2008, is attached hereto as Exhibit 5.

7. A true and correct copy of the Complaint filed on October 29, 2003 by Apotex Inc. in *Apotex Inc. et. al v. Pfizer Inc. et al.* in the U.S. District Court for the District of Delaware in C.A. No. 03-990, is attached hereto as Exhibit 6.

8. A true and correct copy of the Answer filed on January 2, 2008 by Apotex Inc. in *Sanofi Aventis et al. v. Apotex Inc. et al.* in the U.S. District Court for the District of Delaware in C.A. No. 07-792, is attached hereto as Exhibit 7.

9. A true and correct copy of the Answer filed on January 22, 2008 by Apotex Inc. in *Senju Pharmaceutical Co., Ltd. et al. v. Apotex Inc. et al.* in the U.S. District Court for the District of Delaware in C.A. No. 07-779, is attached hereto as Exhibit 8.

10. A true and correct copy of the Answer filed on June 11, 2007 by Apotex Inc. in *Allergan, Inc. v. Apotex Inc. et al.* in the U.S. District Court for the District of Delaware in C.A. No. 07-278, is attached hereto as Exhibit 9.

11. A true and correct copy of the Answer filed on May 30, 2007 by Apotex Inc. in *Medpointe Healthcare Inc. v. Apotex Inc. et al.* in the U.S. District Court for the District of Delaware in C.A. No. 07-204, is attached hereto as Exhibit 10.

12. A true and correct copy of the Answer filed on April 14, 2006 by Apotex Inc. in *Medpointe Healthcare Inc. v. Apotex Inc. et al.* in the U.S. District Court for the District of Delaware in C.A. No. 06-164, is attached hereto as Exhibit 11.

13. A true and correct copy of the Answer filed on February 21, 2008 by Apotex Inc. in *Boehringer Ingelheim Pharmaceuticals, Inc. v. Apotex Inc. et al.* in the U.S. District Court for the District of Delaware in C.A. No. 08-065, is attached hereto as Exhibit 12.

14. A true and correct copy of the Answer filed on May 9, 2006 by Apotex Inc. in *Merck & Co., Inc. v. Apotex Inc.* in the U.S. District Court for the District of Delaware in C.A. No. 06-230, is attached hereto as Exhibit 13.

15. A true and correct copy of pages produced by Apotex Inc. is attached hereto as Exhibit 14 (designated Highly Confidential by Apotex Inc.).

16. **REDACTED**

17. A true and correct copy of the "Paragraph IV" certification letter regarding U.S. Patent No. 6,316,460 sent by Apotex Inc. to AstraZeneca, dated November 5, 2007, is attached hereto as Exhibit 16.

18. A true and correct copy of a letter sent by counsel for defendants, Laurie A. Haynie, Esq., to counsel for plaintiffs, Nathan A. Evans, Esq., dated April 16, 2008, is attached hereto as Exhibit 17 (designated Highly Confidential by Apotex Inc. and Apotex Corp.).

19. A true and correct copy of a letter sent by counsel for defendants, Laurie A. Haynie, Esq., to counsel for plaintiffs, Nathan A. Evans, Esq., dated April 17, 2008, is attached hereto as Exhibit 18 (designated Highly Confidential by Apotex Inc. and Apotex Corp.).

20. A true and correct copy of a WestLaw printout of testimony by Dr. Bernard ("Barry") Sherman before the House of Representatives Committee on House Energy & Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, on May 2, 2007, is attached hereto as Exhibit 19.

21. A true and correct copy of an article from the Economist, titled *Barry Sherman and His Generic-Drug Company, Apotex, Have Put Big Pharma in a Tizzy*, dated April 11, 2002, is attached hereto as Exhibit 20.

22. A true and correct copy of a printout with search results from a Lexis-Nexis search for patent litigations with Apotex as a party since 2002 is attached hereto as Exhibit 21.

23. A true and correct copy of a WestLaw printout of the Federal Circuit decision *Apotex Inc. and Apotex Corp. v. Pfizer Inc.*, 125 Fed. Appx. 987 (Fed. Cir. 2005), is attached hereto as Exhibit 22.

24. A true and correct copy of Internet website pages from the U.S. Census Bureau's fact sheet on Delaware is attached hereto as Exhibit 23.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 21st day April, 2008 at Wilmington, Delaware.

Dana K. Hammond

Dana K. Hammond

Redacted Version Filed: April 28, 2008

CERTIFICATE OF SERVICE

I, hereby certify on this 28th day of April, 2008 I electronically filed the foregoing Redacted Version of DECLARATION OF DANA K. HAMMOND IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT APOTEX INC.'S RULE 12(b)(2) MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION, OR IN THE ALTERNATIVE TO TRANSFER TO THE MIDDLE DISTRICT OF FLORIDA with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

Richard L. Horwitz (#2246)
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The undersigned counsel further certifies that, on April 28, 2008, copies of the foregoing document were also served upon the following individuals in the manner indicated:

Via Email:
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EXHIBIT 1

APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY
SOCIÉTÉ PHARMACEUTIQUE ENTIÈREMENT CANADIENNE

December 4, 2007

Astrazeneca LP
Wilmington, De 19850-5437

and

Astrazeneca AB
S-151 85
Sodertalje, Sweden

and

York Faulkner, Esq.
Finnegan Henderson et al.
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675

Dear Sirs:

Re: Apotex ANDA for Rosuvastatin Calcium Tablets
Para. IV Notice Certification of Invalidity of U.S. Patent No. RE 37,314

Dear Sirs:

This letter supplements our letter dated November 5, 2007 in regard to the patents listed in the Orange Book in connection with Astra Zeneca's CRESTOR® brand of rosuvastatin calcium tablets.

As required by Sections 505(j)(2)(B)(i) and (ii) of the Federal Food, Drug and Cosmetic Act ("Act") (21 U.S.C. § 355(j)(2)(B)(i), (ii)), notice is hereby given to you that the Food and Drug Administration has received an Abbreviated New Drug Application ("ANDA") submitted by Apotex.

In accordance with 21 C.F.R. § 314.95, the following information is hereby provided:

- The ANDA contains the required bioavailability or bioequivalence data.
- The ANDA number for the application is 79-145.
- The established name for the proposed drug product is Rosuvastatin Calcium tablets. The NDA No. is 02-1366.
- The active ingredient, strength, and dosage form of the product are as follows: rosuvastatin calcium 5, 10, 20 and 40 mg tablets.

I. The Orange Book Patents

Patent Listed in OB	Expires per the OB	Certification
6,316,460	04 Aug. 2020	IV
6,858,618	17 Dec. 2021	
RE 37,314	08 Jan. 2016	IV (originally III)

With its ANDA, Apotex submitted a "paragraph IV certification", pursuant to Sections 505(j)(2)(A)(vii)(IV) of the Act (21 U.S.C. § 355(j)(2)(A)(vii)(IV)), that its proposed tablets will not infringe the **6,316,460** patent. Apotex originally filed a "paragraph III" certification with respect to the **RE '314** patent. Apotex is now filing an amended certification with respect to the **RE '314** patent, requesting amendment of its original "paragraph III" certification with respect to the **RE '314** Patent to a "paragraph IV" certification. Apotex is not certifying under Paragraph IV with respect to the **6,858,618** patent.

In accordance with 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §§ 314.95(c)(6)(i), (ii), the factual and legal bases for the paragraph IV certification for the RE '314 patent and the statement that the RE '314 patent is invalid is set forth below.

II. Legal Standards

A claim is invalid if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a).

The consistent criterion of determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art.

Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124 (Fed. Cir. 2000). These three prongs of the criterion for obviousness are sometimes referred to as "suggestion or teaching in the prior art," "motivation," and "reasonable expectation of success." This inquiry is a question of law based on factual inquiries:

> [u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Graham, 383 U.S. at 17-18; *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (2007); see also *Ruiz v. AB Chance Co.*, 234 F.3d 654, 663 (Fed. Cir. 2000) ("Our precedent clearly establishes that the district court must make *Graham* findings before invalidating a patent for obviousness."); *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000). Thus, *Graham* sets out a four-part inquiry comprising not only the three elements of the primary consideration of obviousness (scope and content of the prior art, differences between the prior art and the claims at issue, and level of ordinary skill in the pertinent art), but also evidence of secondary considerations when such evidence is present. *Ruiz*, 234 F.3d at 663; *SIBIA*, 225 F.3d at 1355.

A claim may be proven obvious in view of a single prior art reference, or in view of a combination of prior art references. When the prior art references are combined to invalidate a claim under 35 U.S.C. § 103, there must be some teaching in the prior art that would motivate a person having ordinary skill in the art to do so, but that teaching need not be expressly stated in one or all of the references used to show obviousness. See *KSR*, No. 04-1350, slip. op. at 14. Motivation "may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved." *Ruiz*, 234 F.3d at 665; *Brown & Williamson*, 229 F.3d at 1125.

One of ordinary skill is not bound to use prior art elements for the reasons taught in the prior art. *KSR*, No. 04-1350, slip. op. at 16. The problem itself may

provide the motivation to combine where there is a design need or market pressure. Id.

[When] there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reasons to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance, the fact that a combination was obvious to try might show that it was obvious under section §103.

See *id.* at 17. The person of ordinary skill in the art can be creative and "be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 16-17. There need not be an explicate statement in the prior that suggests combining the references in the particular way claimed, i.e. a clear teaching, suggestion or motivation in the prior art to combine. *KSR*, No. 04-1350, slip. op. at 11. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 17.

Finally, it must also be shown that there existed a reasonable expectation of success in making the necessary combination or modification. However,

> [o]bviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious. For obviousness under § 103, all that is required is a reasonable expectation of success.

In re O'Farrell, 853 F.2d 894, 903-4 (Fed. Cir. 1988) (citations omitted).

Level of Skill in the Art

The hypothetical person of ordinary skill in the art is a person who is not extraordinarily innovative, nor a researcher of inexhaustible patience, but is a person who thinks conventionally in matters affecting the art in which he or she is skilled. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985); accord *Life Techs., Inc. v. Clontech Lab., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000). Ordinary skill means at least the ability to understand the technology

and make modest adaptations or advances. See, e.g., *In re Mahurkar Patent Lit.*, 831 F.Supp. 1354, 1374 (N.D. Ill. 1993), aff'd, 71 F.2d 1573 (Fed. Cir. 1995). "Factors that may be considered in determining level of ordinary skill in the art include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) educational level of active workers in the field." *Ruiz*, 234 F.3d at 666-67 (Fed. Cir. 2000). Typically, courts also credit the hypothetical person of ordinary skill in the art with several years of experience. See, e.g., *E.I. DuPont de Nemours & Co. v. Monsanto*, 903 F.Supp. 680, 751 (D.Del. 1995), aff'd, 92 F.3d 1208 (Fed. Cir. 1996); *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1357-58 (Fed. Cir. 1999) (level of ordinary skill stipulated by parties). The hypothetical person of ordinary skill in the art is assumed to be aware of all pertinent prior art. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Scope and Content of the Prior Art

As a preliminary matter the scope of the prior art must be considered. "Before answering Graham's 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed Cir. 1987), cert. denied, 481 U.S. 1052 (1987). Any disclosure that qualifies as prior art under § 102 can be used in support of a rejection under § 103, including a prior sale or public use that qualifies as prior art under § 102(b). See *In re Kaslow*, 707 F.2d 1366, 1374 (Fed. Cir. 1983); *Ex parte Andresen*, 212 U.S.P.Q. 100, 102 (B.P.A.I. 1981). Relevant prior art is that which is within the field of endeavor of the inventor, or that is reasonably pertinent to the particular problem being addressed by the inventor. *In re Dillon*, 919 F.2d at 694. In addition, a party's admissions can create valid prior art. See, e.g., *Riverwood Int'l Corp.*, 324 F.3d at 1354; *Constant* 848 F.2d at 1570 ("A statement in a patent that something was in the prior is binding on the applicant and patentee for determination of anticipation and obviousness.").

Differences Between the Prior Art and the Claimed Invention

The differences between the prior art and the claimed invention must be ascertained in order to define those aspects of the claimed subject matter as a whole as to which the determination of obviousness or nonobviousness must be made. *Graham*, 383 U.S. at 22-23; see also *Brown & Williamson*, 229 F.3d at 1126 ("The question thus before us is whether one skilled in the art of cigarette design would have recognized at the time of the Luke invention that a reduction in circumference of the thinnest cigarette then on the market would yield a cigarette which burns tobacco more efficiently ...").

Objective Indicia of Non-Obviousness

A court must consider any objective indicia (also called "secondary considerations") of non-obviousness, when present, as they may often be the most probative evidence in the record. *Ruiz*, 234 F.3d at 667; *Rockwell Int'l Corp. v. U.S.*, 147 F.3d 1358, 1366 (Fed. Cir. 1998). Such secondary considerations include commercial success of the invention, whether the invention solved a long felt but unresolved need in the art, copying of the invention by others in the field, initial expressions of disbelief by experts in the field, and failure of others to solve the problem that the inventor solved. See *Graham*, 383 U.S. at 17-18; *Brown & Williamson*, 229 F.3d at 1129. However, for such secondary considerations to be given substantial weight, a nexus must be established between the merits of the claimed invention and the alleged objective indicium of non-obviousness. See, e.g., *In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *SIBIA Neurosciences Inc.*, 225 F.3d at 1358. The patentee bears the burden of establishing a *prima facie* case of such a nexus. Demaco *Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). Evidence of objective indicia of non-obviousness must be commensurate in scope with the claimed invention. See, e.g., *In re Hiniker Co.*, 150 F.3d 1362, 1368-69 (Fed. Cir. 1998); see also *Sandt Tech., Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1355 (Fed. Cir. 2001).

The objective indicia of non-obviousness, however, do not control the analysis when there is an otherwise strong case of obviousness, such as one based upon art not considered by the USPTO during prosecution. See *Sandt*, 264 F.3d at 1355 ("We see no error in the district court's conclusion . . . that the secondary considerations cannot overcome the strong prima facie evidence of obviousness presented."); *Brown & Williamson*, 229 F.3d at 1131.

Patentability Based Upon "Unexpected Advantages"

Title 37 C.F.R. § 1.132 allows a patent applicant to submit evidence in the form of a declaration that the subject matter of the application which appears prima facie obvious over the prior art is in fact non-obvious because it exhibits "unexpectedly superior properties or advantages" over the prior art.

Evidence submitted to show unexpected advantages "must compare the claimed subject matter with the closest prior art." *In re Burckel*, 592 F.2d 1175, 1179 (C.C.P.A. 1979); *In re Gartside*, 203 F.3d 1305, 1320 (Fed. Cir. 2000) (Unexpected results based on tests of a process not within the scope of the claims was not probative of non-obviousness). "When a patent simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR*, No. 04-1350, slip. op. at 13. "A comparison of

the claimed invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference." *In re Merchant*, 575 F.2d 865, 868 (C.C.P.A. 1978). "Though particular results [may] appear unexpected in a comparison with the closest single prior art reference, the teaching of another reference may establish that those results would have been expected by those skilled in the art." *Id.* at 869.

Any evidence relied on to establish unexpected results must also show that "the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." *Ex parte Gelles*, 22 U.S.P.Q. 2d 1318, 1319 (BPAI 1992). When alleged unexpected results relate to a property known in the art to be possessed by similar prior art compositions, it must be shown that these known properties were present to an unexpectedly greater degree. *In re Dillon*, 919 F.2d at 693; *In re Harris*, 409 F.3d 1339,1344 (Fed. Cir. 2005) ("The 32-43% increase in [the claimed alloy's] stress-rupture life, however, does not represent a 'difference in kind' that is required to show unexpected results."); *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996) (claimed ranges must "produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.") (emphasis added). "[D]ata furnished to the patent office to compare performance of the invention with prior art must be fairly and accurately presented since the patent office has no means of verifying the data." *Lam, Inc. v. Johns-Manville Corp.*, 668 F.2d 462, 471 (10th Cir. 1982) (emphasis added). An affidavit offering test data constitutes a representation by the applicant that the showing is "a fair and accurate demonstration of the closest prior art of which he is aware." *Norton v. Curtiss*, 433 F.2d 779, 794 (C.C.P.A. 1970). As with the other secondary considerations, a showing of unexpected results must be commensurate in scope to the claims. *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003).

III. Invalidity of U.S. Reissue Patent No. RE 37,314 E

Claims 6-8 of United States of U.S. Reissue Patent No. RE 37,314 E ("the '314 reissue patent" are directed, respectively, to a non-toxic pharmaceutically acceptable salt of rosuvastatin (claim 6), the sodium salt of rosuvastatin (claim 7), and, the calcium salt of rosuvastatin (claim 8).

Apotex asserts that claims 6-8 the '314 reissue patent are invalid under 35 U.S.C. § 103(a) because they would have been obvious to a person having ordinary skill in the art at the time the alleged invention of those claims was made.

European Patent Application No. 0 367 895 ("EP '895") is prior art to RE '314 because it published more than one year before the earliest effective U.S. filing date of the original application to which RE '314 claims priority. European Patent Application No. EP 0 330 057 ("EP '057") is also prior art to RE '314 because it published more than one year before the earliest effective U.S. filing date to which RE '314 claims priority.

EP '895 discloses a compound that differs from rosuvastatin calcium in that rosuvastatin calcium, at the 2-position of the pyrimidine ring therein, has the substituent of the formula $-N(CH_3)(SO_2CH_3)$ and EP '895 has the substituent of the formula $-N(CH_3)_2$. The compound in EP '895, as discussed below, is also depicted as the sodium salt, not the calcium salt. The compound as disclosed in EP '895 is disclosed as an "especially preferred embodiment". EP '057 discloses structurally analogous compounds to the "especially preferred" compound in EP '895 and the combined teachings of EP '895 and EP '057 suggest to a person having ordinary skill in the art, with a reasonable expectation of success, modification of the EP '895 compound to arrive at rosuvastatin calcium.

Apotex affirmatively states that it may have further bases, in addition to those stated above, supporting its invalidity position under 35 U.S.C. §§ 101 *et seq*, (including §§ 102(a), (c)-(g), § 112 and § 251), and further that additional bases bearing on the validity, noninfringement, and/or enforceability of any of the patents and to which Apotex is required to certify, may develop in the event of litigation between the parties. Apotex expressly reserves the right to assert additional defenses and grounds bearing on the validity, noninfringement, and/or enforceability of the patent in the even of litigation between the parties.

Receipt of this notice begins the 45-day period provided for in Section 505(j)(5)(B)(iii) of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. The ANDA will be amended with a copy of the return receipt for this notice, as required by 21 C.F.R. § 314.95(e).

As a matter of professional courtesy, please send a copy of any complaint filed to Shashank Upadhye, Esq. at:

Mr. Shashank Upadhye, Esq.
Vice President, Global Intellectual Property
Apotex Inc.
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Toronto, Ontario M9L 1T9
Telephone: (416) 401-7701
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With respect to any service of process, the following attorney is authorized to accept service on behalf of Apotex, Corp.

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* * *

Yours very truly,
APOTEX INC.

Bernice Tao
Director, Regulatory Affairs US

EXHIBIT 2

AstraZeneca
INTERNATIONAL

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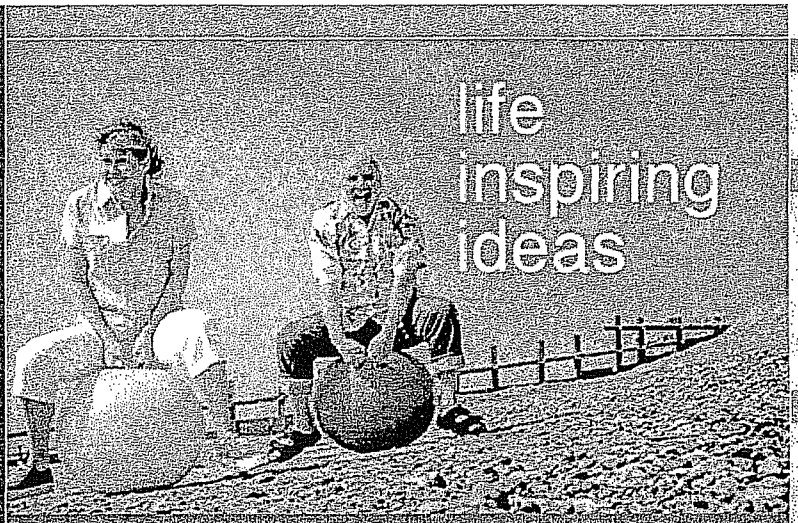

Welcome to AstraZeneca's international website. As one of the world's leading pharmaceutical companies, our business is focused on turning good ideas into innovative, effective medicines that make a real difference in important areas of healthcare.

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- **31 March 2008** : Crestor Outcomes Study JUPITER Closes Early Due To Unequivocal Evidence Of Benefit
- **13 March 2008** : AstraZeneca and Silence Therapeutics To Collaborate On Novel Approaches For siRNA Drug Delivery

Features

- First quarter results 2008 will be announced on Thursday, 24 April 2008
- Annual Report and Form 20-F Information published, Thursday 6 March, and available online as a dedicated website
- Latest corporate responsibility reporting and information about our commitment also published and available online

Information for

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Share price

- London ↓ 20.75 GBP
- New York ↓ 41.29 USD
- Stockholm ↓ 244.50 SEK

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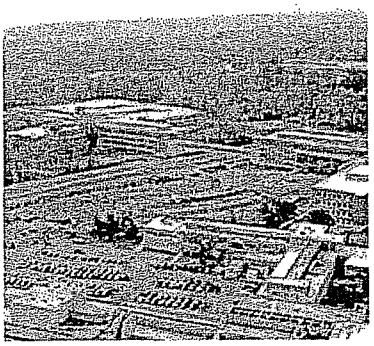
Wilmington, US

R&D Wilmington is located in Wilmington, Delaware, not far from Philadelphia. Research here is focused on pain control, neurology and psychiatry. The site is a centre of excellence in psychiatry, concentrating on developing therapies for schizophrenia, anxiety, depression, bipolar and dementia.

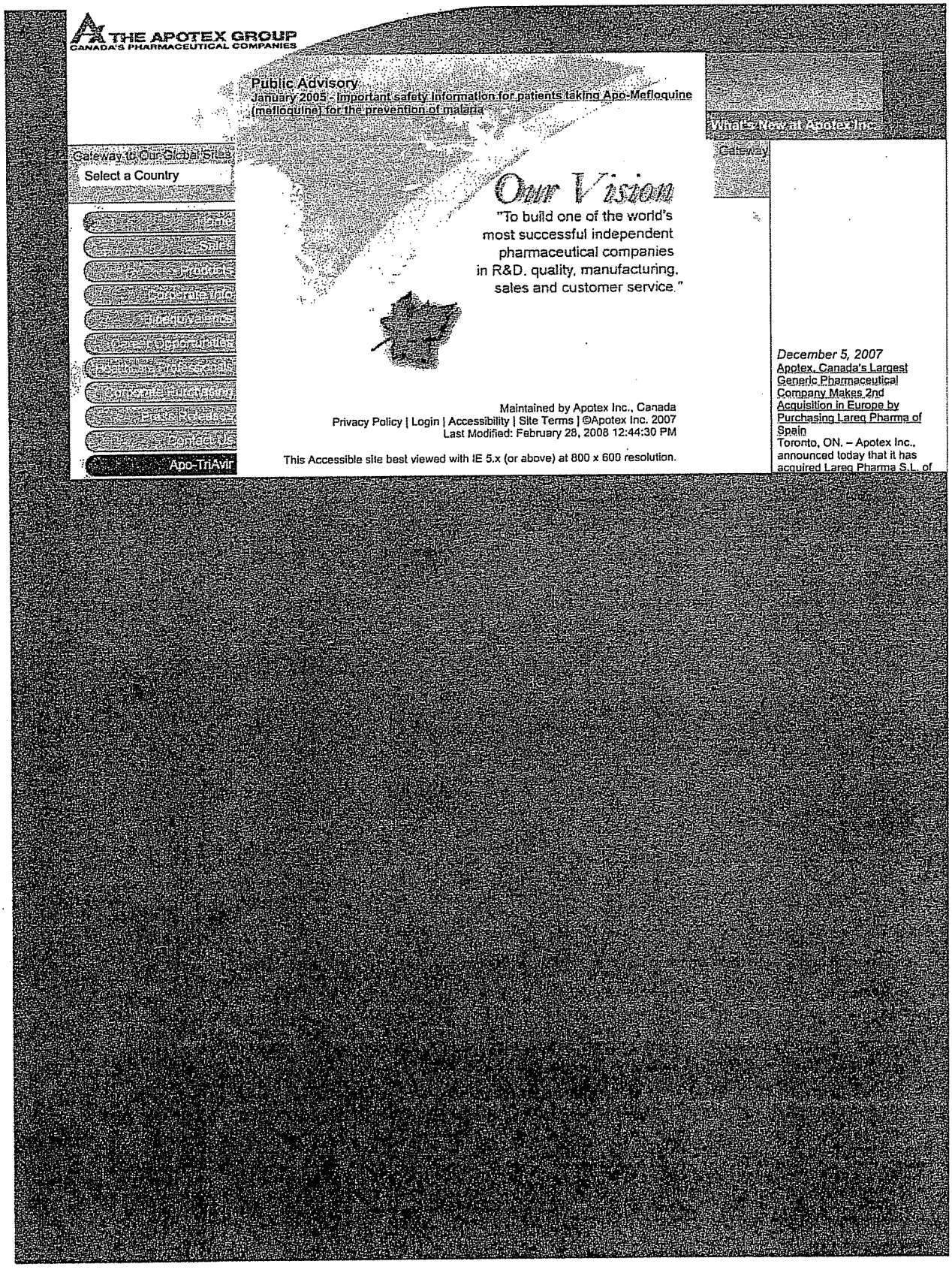


We employ over 2,000 people in R&D in Wilmington, which is also our US Corporate HQ with over 5,000 employees in total.

Zomig , *Seroquel* and *Diprivan* are innovations from our Wilmington laboratories.

Read more about this facility.

EXHIBIT 3


THE APOTEX GROUP
CANADA'S PHARMACEUTICAL COMPANIES
Public Advisory
January 2005 - Important safety information for patients taking Apo-Mefloquine (mefloquine) for the prevention of malaria
What's New at Apotex Inc.
Gateway
Gateway to Our Global Sites
Select a Country
Our Vision
"To build one of the world's most successful independent pharmaceutical companies in R&D, quality, manufacturing, sales and customer service."
Apo-TriAvir
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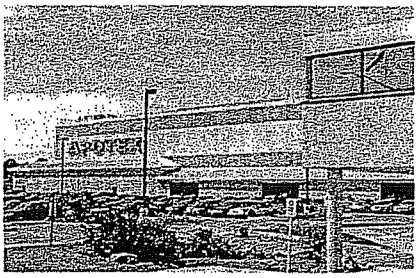
Last Modified: February 28, 2008 12:44:30 PM
This Accessible site best viewed with IE 5.x (or above) at 800 x 600 resolution.
December 5, 2007
Apotex, Canada's Largest Generic Pharmaceutical Company Makes 2nd Acquisition in Europe by Purchasing Lareq Pharma of Spain
Toronto, ON. – Apotex Inc., announced today that it has acquired Lareq Pharma S.L. of

Corporate Overview

As Canada's largest pharmaceutical company, the Apotex Group of Companies together research, develop, manufacture, and market close to 300 generic pharmaceutical products for the Canadian market and around the world. Everyday, we work hard to ensure that every process meets the highest level of quality and customer service anywhere in the Industry.

Richmond Hill Site



Apotex's Richmond Hill Site, is a 390,000 square foot, high quality, modern facility, located just north of Toronto and was purchased by Apotex in April 1998. This purchase has effectively positioned Apotex Inc. to meet future pharmaceutical group business objectives by expanding into the Sterile and Non-Sterile Liquids products.

This modern facility includes dedicated state-of-the-art laboratory, production and packaging equipment. Over 600 highly skilled employees assist in the day-to-day operations of this fully integrated world class operation. Business functions include the areas of Compounding, Filling, Packaging, Research and Development, Product Development, Regulatory Affairs, Quality Management, Engineering/ Facilities, Finance, Information Systems, Human Resources, Materials Management and Distribution / Warehouse. The market focus of this organization remains on the development and manufacturing of Liquid generic pharmaceuticals for sale and export in North America and throughout the world.

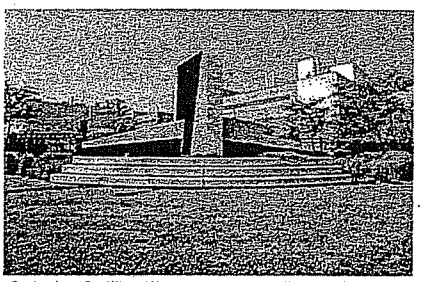
The Richmond Hill Site has capabilities in Sterile products such as Ophthalmics, Injectables, Inhalation Solutions and Non-Sterile products such as Nasal and Oral Solutions.

Canadian Therapeutics Products Directorate (TPD) and U.S. Food and Drug Administration (FDA) and international regulatory agencies' approvals have paved the way for worldwide export and sales of the Richmond Hill Site's unique liquid and specialty dosage forms.

Product Development, Commercial Laboratory operations (CLO) and Microbiology laboratories utilize the latest technology, for example the Product Development and CLO labs employ over a hundered HPLCs and UPLCs to obtain separation science data. Current production capabilities include a number of flexible and high-speed filling lines, a large-capacity area for compounding non-sterile and sterile liquids and a manufacturing suite for inhalation products using blow-fill-seal technology. Sterile products such as ophthalmics and injectables are manufactured and tested using the latest isolation barrier technology and traditional clean rooms. Isolation technology is capable of achieving a greater level of sterility assurance for aseptically filled products. Advanced packaging technology includes bar code labelling systems, tamper evident sealing, child-proof capping capabilities, online shrink wrapping and cartoning, with check-weighing throughout.

From beginning to end, the Richmond Hill Site develops, manufactures and distributes a broad line of quality pharmaceuticals.

Etobicoke Site



The Etobicoke Site of Apotex was established in June of 1993, by Dr. Barry Sherman, to serve as the manufacturing arm of an effort to enter into the U.S. oral solid dosage market, namely tablets and capsules, for Apotex Inc. A major part of the discussion that took place at the time this site was founded centered on where to locate this facility. Enticements by several states in the U.S. and actions by Apotex competitors seemed to indicate that it would have been advantageous to establish a site south of the border. Dr. Sherman ultimately decided that the Etobicoke Site would be founded and operated in Canada to create value and employment here in Canada. A large site was chosen at 50 Steinway Boulevard in Etobicoke, Ontario. Construction was completed on Phase I of the facility in early 1994. From its three-employee, 10,000 square foot beginning, the company has grown to currently employ over 900 people, and occupy 640,000+ square feet of office, warehouse, laboratory and manufacturing space. We are a full function process research and manufacturing facility. We operate according to the strictest world standards for current Good Manufacturing Practices (cGMP) to ensure that only the finest quality products are manufactured. In order to meet these tough manufacturing standards and produce a cost-effective product, we have built one of the most innovative pharmaceutical manufacturing facilities in North America. Many examples of state-of-the-art technology are currently used while others are under development to help maintain the site's leadership and competitive edge.

Early growth and success at this site did not come easily. The lengthy regulatory product-approval process meant that there could be no significant sales in the first several years. Fortunately, the company's commitment and dedication was rewarded in 1997 when the Etobicoke Site received approval on September 12, 1997, for their first U.S. registered product, an anti-ulcer medication, Ranitidine. Since then, there have been numerous approvals; the Etobicoke Site has dozens of products in the registration process with regulatory authorities around the world.

The Etobicoke Site is proud to be breaking new ground by applying innovative technology to pharmaceutical manufacturing. We are setting new standards for pharmaceutical manufacturing across North America with advanced manufacturing processes, innovative technology and the enthusiasm of the our team. We are confident that the Etobicoke Site will continue to be a competitive force in the global pharmaceutical market for many years to come. The recent expansion was recognized as one of the 5 best pharmaceutical facilities in the world.

(2)

About Apotex
Corporate Overview
President's Message
Philanthropy
Press Releases

About Apotex

Apotex Inc. was founded in 1974, and is the largest Canadian-owned pharmaceutical company. From its 2 employees, 5,000 square foot beginning, the company has grown to employ over 6,500 people in research, development, manufacturing and distribution facilities world-wide. The Canadian operations of the Apotex Group of Companies with 5,800 employees now occupy over 3.4 million square feet in Montreal, Richmond Hill, Toronto, Etobicoke, Mississauga, Brantford, Windsor, Winnipeg, London, Calgary and Vancouver. Apotex produces more than 300 generic pharmaceuticals in approximately 4,000 dosages and formats which, in Canada, are used to fill over 85 million prescriptions a year - the largest amount of any pharmaceutical company in this country.

Today, Apotex is a necessary and trusted member of Canada's healthcare community. The company's pharmaceuticals can be found in virtually every pharmacy and healthcare facility in Canada and are exported to over 115 countries around the globe. Export markets represent an ever growing portion of the total sales. Apotex has also established a presence through subsidiaries, joint ventures or licensing agreements in Australia, Belgium, Czech Republic, Italy, Mexico, Netherlands, New Zealand, Poland, Turkey, and the UK, to name just a few. Healthcare professionals around the world rely on Apotex for quality and value.

Although the company's own business is developing and manufacturing generic pharmaceuticals, the success of Apotex has enabled it to diversify into a number of other health-related areas. The Apotex Pharmaceutical Group of Companies also researches, develops, manufactures and distributes fine chemicals, non-prescription and private label medicines, and disposable plastics for medical use.

The worldwide sales of the Apotex Group of companies exceed $1 billion (Canadian $) per year.

(3)

THE APOTEX GROUP
CANADA'S PHARMACEUTICAL COMPANY

CORPORATE INFO

Select a Country

Apo-TriAvir

Printer Friendly Version

Apotex Inc. was founded in 1974, and is the largest Canadian-owned pharmaceutical company. From its 2 employees, 5,000 square foot beginning, the company has grown to employ over 6,500 people in research, development, manufacturing and distribution facilities world-wide. The Canadian operations of the Apotex Group of Companies with approximately 5,800 employees now occupy over 3.4 million square feet in Montreal, Richmond Hill, Toronto, Etobicoke, Mississauga, Brantford, Windsor, Winnipeg, Calgary and Vancouver.

In the last few years, Apotex has hired over 1200 new employees in Production, Engineering, Operations, Quality and Research. Out of the total employee base, there are over 2,100 scientific staff including over 110 PhD's. To meet the growing world demand for Apotex medicines, hundreds of new qualified technical professionals need to be hired. Apotex produces more than 300 generic pharmaceuticals in over 4000 dosages and formats which, in Canada, are used to fill over 85 million prescriptions a year - the largest amount of any pharmaceutical company in this country.

→Chairman's Message

→President's Message

"Apotex believes that every man, woman and child is entitled to affordable healthcare and freedom from unnecessary pain and suffering."

View Our Corporate Video

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→Leading the Way With Research and Development

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Press Release

December 5, 2007
Attn: Business Editors
For Immediate Release

Apotex, Canada's Largest Generic Pharmaceutical Company Makes 2nd Acquisition in Europe by Purchasing Lareq Pharma of Spain

Toronto, ON (December 5, 2007) — Apotex Inc., announced today that it has acquired Lareq Pharma S.L. of Spain for an undisclosed sum from Industria Quimica Y Farmaceutica VIR S.A.

Lareq, founded in 1984 and dedicated to generics since 1996, is a mid-sized generic pharmaceutical company. With 12 generic registrations, several pending near-term launches and products in development, Lareq is the 13th largest player in the retail pharmacy generics segment. It benefits from strong brand recognition amongst pharmacists, and a nation-wide sales force that reaches Spain's retail pharmacies.

The Spanish pharmaceutical market is the 5th largest in the EU and ranks 7th in the world, valued at almost 13 billion Euros. The generics segment represents 9% of the total market, growing 16.6% compared to 7.6% for the overall pharmaceutical market in 2006.

"The Spanish generics market is a fast-growing market and all the major international generics competitors are present here – it is a key market for us as we establish ourselves as a recognized global generic player", says Andrew Kay, President of Apotex International.

The Spanish acquisition represents an important milestone for Apotex International as it extends the organization's foothold in Western Europe and is a launching pad for the many EU products currently in the development pipeline at Apotex.

Just recently, Apotex announced the acquisition of Topgen of Belgium from the Zambon Group. "The acquisitions in Belgium and Spain, as well as our new affiliate in Turkey, are clear signals of our commitment to growth outside Canada and the US" continues Andrew Kay.

Besides the aforementioned countries, Apotex International Inc. has an affiliate presence in Australia, New Zealand, Central America, Mexico, Czech Republic, Italy, Netherlands, Poland and the UK.

Apotex Inc. is the largest Canadian-owned pharmaceutical company, employing over 6,800 people in research, development, manufacturing and distribution facilities world-wide. Apotex produces more than 300 generic pharmaceuticals in approximately 4,000 dosages and formats which, in Canada, are used to fill over 75 million prescriptions a year - the largest amount of any pharmaceutical company in this country. In the next 10 years, Apotex will spend $2 Billion in R&D and has presently 602 products under development.

-30-

For further information:

Mr. Elie Betito
Director Public & Government Affairs
Tel: 416-749-9300 Ext. 7366
Cell: 416-558-5491
ebetito@apotex.com

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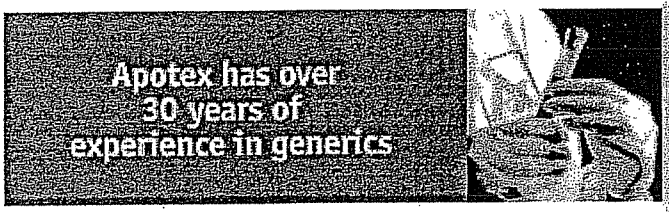


About Apotex

» Apotex at a Glance
» A Message From Our President
» Our Corporate Background

APOTEX at a glance

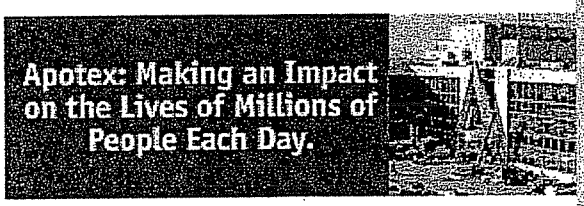
We are an innovative global research and technology leader in generic pharmaceuticals, serving 115 countries worldwide. As the largest Canadian-owned pharmaceutical company, we serve the U.S. market with a promise and commitment to our customers to make their needs our priority.

At Apotex, we are dedicated to providing world class manufacturing, biotechnology research and distribution technologies to meet the needs of the U.S. generic pharmaceuticals market.

Everything we do is founded on frequent, open dialogue with our customers, backed by over 30 years of experience. If you haven't had a pharmaceutical provider respond to your needs, you have now.

Welcome to Apotex.

6



About Apotex

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CORPORATE background

Apotex, Inc., founded in 1974, has grown to an international effort, with more than 260 generic pharmaceutical products in approximately 4000 dosages and formats, distributed worldwide.

Apotex is making an impact on the lives of hundreds of millions of people every day and is committed to being one of the world's leading suppliers of quality, affordable generic products.

As a diversified, vertically integrated provider we are dedicated to excellence in everything we do, from biotechnology research to innovative packaging. Our subsidiaries cover a range of manufacturing capabilities including active ingredients, packaging components, medical devices, capsule technology and unique drug delivery systems. Apotex Etobicoke, located in Etobicoke, Ontario, manufactures most U.S. tablet and capsule pharmaceutical products, and Apotex Richmond Hill, located in Richmond Hill, Ontario, manufactures and packages liquids, aerosols, ophthalmics, injectables, form-fill and seal unit dose packaging.

Today, our mandate is simple: to research, develop, manufacture and market affordable, safe and effective quality generic pharmaceuticals.

Our goal is to develop strong partnerships with our customers through innovative professional programs, education and practice-based research.

(7)

APOTEX **Products** | United States

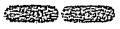
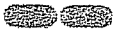
quinapril Search Advanced Search

Our Products
All Products
New Products
Injectable Products
Specialty Products

Advanced Search
Downloads

Back to main page

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Product Name (Active Ingredients)	Strength	Image (Not to scale)	NDC Number	TE Rating	Pack Size	Brand Reference	Detail
Quinapril Tablets USP (Quinapril)	5 MG		60505-0172-00	AB	90 TABLET	ACCUPRIL®	Detail
			60505-0172-01	AB	1000 TABLET	ACCUPRIL®	Detail
	10 MG		60505-0173-00	AB	90 TABLET	ACCUPRIL®	Detail
			60505-0173-01	AB	1000 TABLET	ACCUPRIL®	Detail
	20 MG		60505-0174-00	AB	90 TABLET	ACCUPRIL®	Detail
			60505-0174-01	AB	1000 TABLET	ACCUPRIL®	Detail
	40 MG		60505-0175-00	AB	90 TABLET	ACCUPRIL®	Detail
			60505-0175-01	AB	1000 TABLET	ACCUPRIL®	Detail

This search returned 8 results.

8

EXHIBIT 4
Fully Redacted

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. APOTEX INC., and APOTEX CORP., Defendants.	Civil Action No.: 07-809-JJF-LPS

DEFENDANT APOTEX INC.'S OBJECTIONS AND RESPONSES TO PLAINTIFF'S INTERROGATORIES RELEVANT TO JURISDICTIONAL DISCOVERY

Pursuant to Fed.R.Civ.P. 33(b), Defendant Apotex Inc. ("Defendant" or "Apotex Inc.") hereby submits its Objections and Responses to Plaintiffs' Interrogatories to Apotex Relevant to Jurisdictional Discovery (Nos. 1-6) as follows:

GENERAL OBJECTIONS

1. Defendant objects to the Definitions and interrogatories to the extent that they seek information or documents protected by the Attorney-Client Privilege or that qualify as Attorney Work Product, prepared in connection with settlement discussions, prepared in anticipation of litigation or for trial, or that are subject to any other applicable privilege, protection, immunity or restriction upon discovery, or because they otherwise call upon Defendant to disclose the mental impressions, conclusions, considerations, opinions, or the legal theories of attorneys or other representatives of Defendant concerning this or any other litigation.

Inadvertent disclosure of any privileged or protected information or documents in response to these interrogatories shall not be deemed a waiver of the applicable privilege or protection, or of any other basis for objection to discovery, or of the right of Defendant to object to the use, and see the return, of any such inadvertently disclosed information.

2. Defendant objects to the Definitions and interrogatories to the extent that they are not within the scope of permissive discovery under the Federal Rules of Civil Procedure. Defendant will respond only to the extent required by the Rules.

3. Defendant objects to the Definitions and interrogatories to the extent that they seek to impose an improper or undue burden or a burden that exceeds that contemplated by the Federal Rules of Civil Procedure. Defendant will respond only to the extent required by the Rules.

4. Defendant objects to the Definitions and interrogatories to the extent that they are overly broad and seek disclosure of information or documents that are neither relevant to the subject matter of this investigation nor reasonably calculated to lead to the discovery of admissible evidence, or are in any other way inconsistent with the Federal Rules of Civil Procedure. Defendant will respond to the interrogatories only to the extent required by the Rules.

5. Defendant objects to Plaintiffs' definition of "Apotex Inc." and "Apotex" to the extent that the definition includes persons or entities that are separate and distinct from Defendant and over which Defendant exercises no control; to the extent that the definition does not comport with the Federal Rules of Civil Procedure; and to the extent that the definition includes any entity other than Defendant Apotex Inc. Accordingly, where appropriate, all

responses to these interrogatories are based on information within the possession and/or control of Defendant Apotex Inc. only.

6. Defendant objects to Plaintiffs' interrogatories to the extent that they require Defendant to identify or make discovery responses based on any activity relating to rosuvastatin calcium drug product that is protected from patent infringement liability under 35 U.S.C. § 271(e)(1).

7. Defendant objects to the interrogatories to the extent that they use terms that are not defined or understood, or are vaguely or ambiguously defined, and therefore fail to identify with reasonable particularity the information sought. Defendant will not speculate as to the meaning to ascribe to such terms.

8. Defendant objects to the Definitions and interrogatories to the extent they seek to impose an obligation on Defendant to disclose information that is publicly available and/or as easily obtained by other parties as Defendant, or that is more appropriately obtained through sources other than interrogatories, on the grounds that such discovery is overly broad and unduly burdensome. Defendant also objects to the interrogatories to the extent that they seek information or documents that are already known to or in the possession of Plaintiffs.

9. Defendant objects to the interrogatories to the extent that they seek information that is Defendant's confidential business information or that is subject to confidentiality restrictions of a third party.

10. Defendant generally objects to the interrogatories to the extent they call for legal conclusions of questions of law.

11. Defendant incorporates by reference the general objections set forth above into each of its responses, whether or not repeated therein, as well as any specific stated objections.

Defendant may repeat a general objection for emphasis or some other reason, but the failure to repeat any general objection does not waive any general objection to the interrogatories. Defendant does not waive its right to amend its objections. Defendant's willingness to provide the requested responses or information is not an admission that such responses or information are relevant or admissible.

12. Defendant's responses are based on information currently available to Defendant based upon a reasonable investigation. Investigation and discovery are ongoing. Defendant reserves all rights to supplement, revise and/or amend these responses should additional information become available through the discovery process or other means. Defendant also reserves the right to produce or use any information or documents that are discovered after service of these responses in support of or in opposition to any motion, in depositions, or in hearings. In responding to Plaintiffs' interrogatories, Defendant does not waive any objection on the grounds of privilege, competency, relevance, materiality, authenticity, or admissibility of the information contained in these responses.

RESPONSES TO INTERROGATORIES

Interrogatory No. 1 Identify each Apotex drug product sold in the United States during the past five years, and state the annual volume of sales in the United States during the past five years.

> **Response:** Defendant objects to this interrogatory because Apotex Inc. does not currently sell and has not sold any drug product in the United States during the past five years. Subject to and without waiving this objection and Defendant's General Objections, *see* Response to Interrogatory No. 1 of Defendant Apotex Corp.'s Objections and Response to Plaintiff's Interrogatories Relevant to Jurisdictional Discovery.

Interrogatory No. 2 Identify each Apotex drug product sold into Delaware by Apotex during the past five years; state the annual volume of all such sales into Delaware during the past five years; and identify the Apotex entity making the sales into Delaware.

> **Response:** Subject to and without waiving its General Objections, Apotex Inc. does not currently sell and has not sold any drug product into Delaware during the past five years.

Interrogatory No. 3 Identify each Apotex drug product sold into Delaware by Apotex's distributors, wholesalers, resellers, agents or other persons during the past five years; state the annual volume of all such sales into Delaware during the past five years; and identify the distributors, wholesalers, resellers, agents, or other persons making the sales into Delaware.

> **Response:** Defendant objects to this interrogatory because Apotex Inc. does not have any distributors, wholesalers, resellers, agents or other persons who have sold Apotex drug product into Delaware during the past five years. Subject to and without waiving this objection and Defendant's General Objections, *see* Response to Interrogatory No. 3 of Defendant Apotex Corp.'s Objections and Response to Plaintiff's Interrogatories Relevant to Jurisdictional Discovery.

Interrogatory No. 4 Identify and describe all supply chains and distribution channels used by Apotex and/or its distributors, wholesalers, resellers, agents, or other persons to bring Apotex drug products described in Interrogatory Nos. 2 and 3 from the point of manufacture into Delaware, including all warehouses, storage sites, shipping centers, or other locations.

> **Response:** Defendant objects to this interrogatory because Apotex Inc. does not have any distributors, wholesalers, resellers, agents or other persons who have sold Apotex drug products described in Interrogatory Nos. 2 and 3 into Delaware. Subject to and without waiving this objection and Defendant's General Objections, *see* Response to Interrogatory No. 4 of Defendant Apotex Corp.'s Objections and Response to Plaintiff's Interrogatories Relevant to Jurisdictional Discovery.

Interrogatory No. 5 Identify and describe all contractual or other business relationships between Apotex, on the one hand, and, on the other hand, any person, corporation, government, attorney, law firm, or other organization that is either located in Delaware or transacts business in Delaware for Apotex.

Response: Subject to and without waiving its General Objections, and other than those attorneys and law firms identified in response to Interrogatory No. 6 who represent Apotex Inc. in connection with the litigation identified in Interrogatory No. 6, Apotex Inc. has no contractual or other business relationships with any person, corporation, government, attorney, law firm, or other organization located in Delaware or who transacts business in Delaware for Apotex Inc.

Interrogatory No. 6 Identify each litigation initiated in or transferred to Delaware in which Apotex has participated in the last five years that was provoked by a paragraph IV certification filed by or on behalf of Apotex with respect to an ANDA filed by or on behalf of Apotex, and separately as to each state: (a) the period of time the action was pending, (b) the judge to whom it was assigned, (c) whether Apotex moved to dismiss the action for lack of personal jurisdiction over Apotex, Inc., (d) the identity of any lawyer licensed to practice in Delaware retained by Apotex in connection with that action, and (e) the identity of any other entity from whom Apotex purchased any goods or services in Delaware in connection with each such action.

Response: Subject to and without waiving its General Objections, Apotex Inc. responds as follows:

1. *Apotex Inc., et al v. Pfizer Inc., et al*, Case No. 1:03-CV-00990-SLR
   a. October 29, 2003 – September 19, 2006
   b. Judge Sue L. Robinson
   c. No
   d. Steven J. Balick
      Ashley & Geddes
      500 Delaware Avenue, 8th Floor
      P.O. Box 1150
      Wilmington, Delaware 19899
   e. None

2. *MedPointe Healthcare Inc. v. Apotex Inc. et al*, Case No. 1:06-CV-00164-SLR
   a. March 10, 2006 – present
   b. Judge Sue L. Robinson
   c. No
   d. Richard L. Horwitz, Kenneth L. Dorsney
      Potter, Anderson & Corroon LLP
      Hercules Plaza – Sixth floor
      1313 North Market Street
      Wilmington, Delaware 19801
   e. None

3. *Merck & Co., Inc. v. Apotex Inc.*, No. 06-230-GMS
   a. April 7, 2006 – May 21, 2007
   b. Judge Gregory M. Sleet
   c. No
   d. Richard L. Horwitz, Kenneth L. Dorsney
      Potter, Anderson & Corroon LLP
      Hercules Plaza – Sixth floor
      1313 North Market Street
      Wilmington, Delaware 19801
   e. None

4. *MedPointe Healthcare Inc. v. Apotex Inc. et al*, Case No. 1:07-CV-00204-SLR
   a. April 17, 2007 – present
   b. Judge Sue L. Robinson
   c. No
   d. Richard L. Horwitz, Kenneth L. Dorsney
      Potter, Anderson & Corroon LLP
      Hercules Plaza – Sixth floor
      1313 North Market Street
      Wilmington, Delaware 19801
   e. None

5. *Allergan Inc. v. Apotex Inc. et al*, Case No. 1:07-CV-00278-GMS
   a. May 21, 2007 – present
   b. Judge Gregory M. Sleet
   c. No
   d. Richard L. Horwitz, Kenneth L. Dorsney
      Potter, Anderson & Corroon LLP
      Hercules Plaza – Sixth floor
      1313 North Market Street
      Wilmington, Delaware 19801
   e. None

6. *Purdue Pharma LP et al v. Apotex Inc. et al*, No. 1:07-CV-00549-SLR
   a. September 12, 2007 – November 19, 2007
   b. Judge Sue L. Robinson
   c. Case was dismissed before Answer was filed
   d. Richard L. Horwitz, Kenneth L. Dorsney
      Potter, Anderson & Corroon LLP
      Hercules Plaza – Sixth floor
      1313 North Market Street
      Wilmington, Delaware 19801
   e. None

7. *Senju Pharmaceutical Co. Ltd. et al v. Apotex Inc. et al*, No. 1:07-CV-00779-SLR
   a. November 29, 2007 – present

b. Judge Sue L. Robinson
c. No
d. Francis J. Murphy
Murphy & Landon
1011 Centre road, Suite 210
Wilmington, Delaware 19805
e. None

8. *Sanofi-Aventis et al v. Apotex Inc. et al*, No. 1:07-CV-00792-GMS-MPT
a. December 6, 2007 – present
b. Judge Gregory M. Sleet
c. No
d. Richard L. Horwitz, Kenneth L. Dorsney
Potter, Anderson & Corroon LLP
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Wilmington, Delaware 19801
e. None

9. *AstraZeneca Pharmaceuticals LP et al v. Apotex Inc. et al*, No. 1:07-CV-00809-JJF-LPS
a. December 11, 2007 – present
b. Judge Joseph J. Farnan
c. Yes
d. Richard L. Horwitz, Kenneth L. Dorsney
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e. None

10. *Boehringer Ingelheim Pharmaceuticals Inc. v. Apotex Inc. et al*, No. 1:08-CV-00065-SLR
a. January 1, 2008
b. Judge Sue L. Robinson
c. No
d. Jonathan L. Parshall
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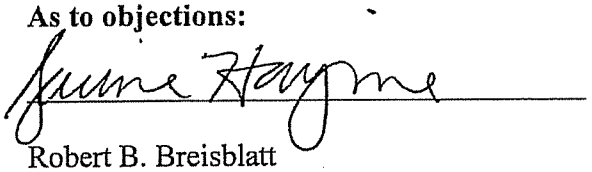
Suite 210
Wilmington, Delaware 19805
e. None

Dated this 2nd day of April, 2008.

As to objections:



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Attorneys for Apotex Inc.

VERIFICATION UNDER 28 U.S.C. § 1746

[TO BE PROVIDED HEREAFTER]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on April 2, 2008, the attached document was electronically mailed to the following person(s):

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EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TORPHARM, INC., APOTEX CORP., and APOTEX, INC. Plaintiffs, v. PFIZER INC., and WARNER-LAMBERT COMPANY (n/k/a WARNER-LAMBERT LLC) Defendants.	)	Civil Action No. 03-990

COMPLAINT FOR DECLARATORY JUDGMENT
AND DEMAND FOR JURY TRIAL

The Plaintiffs, TorPharm, Inc., Apotex Corp., and Apotex, Inc. (collectively "TorPharm"), for their Complaint against Defendants Pfizer Inc. and Warner-Lambert Company (n/k/a Warner-Lambert LLC) (collectively "Pfizer"), allege as follows:

Nature Of The Action

1. This action for declaratory judgment of patent noninfringement arises, *inter alia*, out of TorPharm's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Pfizer's blockbuster drug Accupril® (quinapril hydrochloride). FDA approval of TorPharm's ANDA is imminent.

2. Pfizer owns U.S. Patent No. 4,743,450 ("the '450 patent"), which discloses and claims, *inter alia*, a quinapril pharmaceutical composition. Pfizer has listed the '450 patent in the FDA's "Orange Book" and, as a consequence, maintains that the '450 patent claims the approved drug, Accupril® (quinapril hydrochloride); and that a claim for patent infringement

could reasonably be asserted against any ANDA applicant attempting to market a generic quinapril product. Pfizer, moreover, has enforced and continues to vigorously enforce its intellectual property rights on blockbuster drugs against TorPharm and others, and has already sued and obtained a judgment of infringement on the '450 patent against another generic quinapril applicant.

3. TorPharm has designed around the '450 patent with its proposed quinapril product and so, as required by statute, has certified to the FDA that its product will not infringe the '450 patent and further notified Pfizer of the legal and factual bases for that certification. TorPharm's certification to the '450 patent constitutes a technical or artificial act of infringement under the Hatch-Waxman Act putting TorPharm at considerable risk of being sued by Pfizer both before and after market entry. Pfizer has not yet responded to the submission of TorPharm's ANDA and certification that TorPharm does not infringe. Moreover, Pfizer has not informed TorPharm that TorPharm does not infringe the '450 patent and has not covenanted not to sue TorPharm for infringement of the '450 patent.

4. On information and belief, Pfizer believes that a claim for infringement could be reasonably asserted against TorPharm and Pfizer intends to sue TorPharm for infringement of the '450 patent. There is an actual, substantial, and continuing justiciable case and controversy between TorPharm and Pfizer regarding infringement of the '450 patent, for which this Court can declare the rights of the parties. TorPharm is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril product does not and will not infringe the '450 patent.

The Parties

5. Plaintiff TorPharm, Inc. is a corporation duly organized and existing under the laws of Canada and having its principal place of business in Etobicoke, Ontario, Canada. TorPharm develops, manufactures and markets generic drugs, and in particular solid oral dosage forms such as capsules and tablets, for sale and use in the United States following FDA approval.

6. Plaintiff Apotex Corp. is a corporation incorporated and existing under the laws of the State of Delaware, having a place of business at 616 Heathrow Drive, Lincolnshire, Illinois 60069. Apotex Corp. is the United States marketing and sales affiliate for TorPharm. Following FDA approval of an ANDA, TorPharm manufactures and supplies generic drug products to Apotex Corp., which then markets and sells those products to large wholesalers, warehousing chains, mail order organizations, and distributors in the United States. Apotex Corp. also acts as TorPharm's U.S. agent for purposes of making regulatory submissions, including ANDAs, to the FDA.

7. Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada and having its principal place of business at 150 Signet Drive, Weston, Ontario, Canada M9L 1T9.

8. Plaintiffs TorPharm, Inc., Apotex Corp., and Apotex, Inc. are collectively referred to in this Complaint as "TorPharm."

9. On information and belief, Defendant Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York, 10017-5575.

10. On information and belief, Defendant Warner-Lambert Company was or is a Delaware corporation with a place of business at 201 Tabor Road, Morris Plains, New Jersey 07950. On information and belief, Warner-Lambert Company became a wholly-owned

subsidiary of Pfizer Inc. as of June 19, 2000. On information and belief, Warner-Lambert Company subsequently became Warner-Lambert LLC, a limited liability company incorporated under the laws of the State of Delaware, having its principal place of business at 201 Tabor Road, Morris Plains, New Jersey 07950.

11. Defendants Pfizer Inc. and Warner-Lambert Company are collectively referred to in this Complaint as "Pfizer."

Jurisdiction And Venue

12. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

14. There exists a substantial and continuing actual, justiciable case or controversy between TorPharm and Pfizer regarding infringement of the '450 patent.

15. This Court may declare the rights and legal relations of the parties regarding noninfringement of the '450 patent pursuant to, *inter alia*, 28 U.S.C. §§ 2201, 2202.

16. This Court has personal jurisdiction over Pfizer Inc. and Warner-Lambert Company (n/k/a Warner-Lambert LLC) because they both reside and are located in this District and because they both conduct substantial business in, and have regular and systematic contact with, this District.

17. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Statutory Scheme For Approval Of New And Generic Drugs

18. The approval of new and generic drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman").

New drugs and patent listing requirements

19. Before marketing an original new drug (*i.e.*, not a generic drug) in the United States, Hatch-Waxman requires that an applicant submit, and that FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

20. An NDA applicant is required, within its NDA, to submit information (*i.e.*, *inter alia*, the patent number and expiration date) regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1).

21. FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

22. By filing an NDA and listing a patent in the Orange Book, the NDA-holder and/or patentee, by law, necessarily maintains that the listed patent claims the approved NDA drug and

that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, sale or use of the drug.

23. In other words, the NDA-holder and/or patentee necessarily puts all prospective generic ANDA-filers on notice that a suit for infringement can and will be asserted against any ANDA-filer that attempts to seek approval for and market a generic version of the NDA drug.

24. Such conduct by the NDA-holder and/or patentee gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit or the threat of one if it attempts to seek approval for or to market a generic version of the NDA drug.

Generic drugs and patent certification requirements

25. Hatch-Waxman provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-cost generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

26. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already approved NDA drug by submitting an ANDA to the FDA under 21 U.S.C. § 355(j).

27. Instead of repeating the comprehensive, extensive human studies conducted for the previously approved NDA drug, a generic applicant submitting an ANDA is only required to establish, among other details, that its proposed generic product is bioequivalent to the already approved NDA drug (*i.e.*, has no significant difference in rate and extent of absorption) and that

it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

28. An ANDA applicant is also required to address each patent listed in the Orange Book in connection with the approved NDA drug. In particular, Hatch-Waxman requires an ANDA applicant to submit one of four types of patent certifications for each listed patent: (I) that the NDA-holder has not submitted any patent information to FDA; (II) that the listed patent(s) has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date (commonly referred to as a "paragraph III certification"); or, (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent.

29. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder and the patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice must contain a detailed statement of the factual and legal basis for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(ii).

30. The submission of a paragraph IV certification for a listed patent constitutes an artificial or technical act of infringement that creates the necessary subject matter jurisdiction to enable a patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

31. Upon receipt of the notice of the paragraph IV certification for the listed patent submitted by the ANDA applicant, the NDA-holder/patent owner may file suit for infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A) within forty-five (45) days of receiving such notification.

32. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of generic drug products.

33. Congress intended that the generic manufacture and marketing of a drug should be allowed as soon as it is determined that the particular drug does not violate patent rights, and should not be delayed just because the patentee has not sued the generic applicant first, but rather has merely held its patents over the generic applicant like a modern-day "Sword of Damocles."

34. Congress therefore contemplated that ANDA-filers must obtain a favorable court decision on the patent in order to market the generic drug. This can be accomplished by either being sued by the NDA-holder/patentee within the 45-day period or by the generic ANDA-filer seeking a declaratory judgment of patent infringement and/or invalidity.

35. An ANDA-filer is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder may bring suit after receiving notification of the ANDA and paragraph IV certification. Congress, however, clearly intended that a

declaratory judgment action be available for ANDA-filers who are not sued by the NDA patentee within the 45-day period.

36. The acts of an NDA-holder/patentee listing a patent in the Orange Book through the filing of an NDA and a generic manufacturer filing an ANDA together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement and/or invalidity.

Pfizer's Accupril® (Quinapril Hydrochloride)

37. On information and belief, Pfizer Inc. is the holder of approved NDA No. 19-885 for quinapril hydrochloride tablets, which are sold under the brand-name Accupril®.

38. Accupril® (quinapril hydrochloride) is indicated for the treatment of hypertension and as adjunctive therapy in the management of heart failure.

39. On information and belief, Warner-Lambert Company purports and claims to be the owner of U.S. Patent No. 4,743,450 ("the '450 patent"), the term of which expires on or about August 24, 2007. The '450 patent recites a quinapril pharmaceutical formulation containing a metal-containing stabilizer and a saccharide which minimize the cyclization, hydrolysis and coloration of certain ACE inhibitors, including quinapril. A true and correct copy of the '450 patent is attached to this Complaint as Exhibit A.

40. On information and belief, Pfizer purports and claims to have the right to enforce the '450 patent.

41. Pfizer submitted information on the '450 patent to FDA for placement in the Orange Book. By virtue of that submission, the FDA listed the '450 patent in the Orange Book in connection with Pfizer's approved NDA for Accupril® (quinapril hydrochloride) tablets.

42. By listing the '450 patent in the Orange Book, Pfizer maintains that the '450 patent claims Accupril® (quinapril hydrochloride) tablets and that an infringement suit could reasonably be asserted against any generic ANDA-filer that attempts to seek approval for and market a generic version of quinapril.

TorPharm's ANDA For Quinapril Hydrochloride Tablets

43. On September 13, 2001, TorPharm submitted an ANDA to the FDA seeking approval to market a generic version of Accupril® (quinapril hydrochloride) tablets in 5 mg, 10 mg, 20 mg, and 40 mg strengths. That ANDA was received by the FDA on September 20, 2001 and was assigned ANDA number 76-240 by the FDA ("ANDA No. 76-240").

44. TorPharm's ANDA sought permission to market quinapril hydrochloride tablets for the treatment of hypertension and as adjunctive therapy in the management of heart failure.

45. As part of its ANDA No. 76-240, TorPharm submitted a paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certifying to FDA that the '450 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of TorPharm's quinapril hydrochloride tablets.

46. On information and belief, the FDA's review of TorPharm's ANDA No. 76-240 will be completed in the near future and approval is imminent.

47. TorPharm intends and is prepared to market its generic quinapril product before expiration of the '450 patent.

48. On or about November 15, 2001, in accordance with 21 U.S.C. §§ 355(j)(2)(B)(i),(ii), TorPharm provided Pfizer with notice that it submitted a quinapril ANDA and a paragraph IV certification to the '450 patent. This notice included a detailed statement setting forth the factual and legal bases why the '450 patent will not be infringed by the

manufacture, use, offer for sale, sale, or importation of TorPharm's quinapril hydrochloride tablets.

Pfizer's Litigious Conduct And Vigorous Enforcement Of Its Intellectual Property Rights

49. Pfizer has a long history and program of vigorously enforcing its patents against generic drug applicants, including TorPharm.

50. For example, Pfizer (and its predecessors) have sued numerous ANDA-filers for alleged infringement of patents covering its blockbuster drug Zoloft®. (*Pfizer v. Zenith Goldline Pharms., Inc.*, 00-CV-0408 (D.N.J.)).

51. Pfizer (and its predecessors) have also sued ANDA-filers for alleged infringement of patents covering its blockbuster drug Norvasc®. (*Pfizer v. Dr. Reddy's Labs.*, 02-CV-2829 (D.N.J.)).

52. Pfizer (and its predecessors) also filed suit against a generic competitor regarding Pfizer's drug Procardia XL® (nifedipine). (*Bayer AG, et al. v. Mylan Labs.*, 97-CV-1309 (W.D. Pa.)).

53. Similarly, Pfizer (and its predecessors) have sued ANDA-filers for alleged infringement of patents covering Pfizer's drug Glucotrol XL® (glipizide). (*Pfizer Inc. v. Andrx Corp.*, 01-CV-3260 (D.N.J.)).

54. Pfizer (and its predecessors) also sought to protect its drug Diflucan® (fluconazole) from generic competition by filing suit against ANDA-filers. (*Pfizer Inc. v. Novopharm Ltd.*, 00-CV-1475 (N.D. Ill.)).

55. Pfizer (and its predecessors) have further sued at least eight ANDA-filers, including TorPharm, in numerous Districts for alleged infringement of three patents purportedly covering Pfizer's drug Neurontin® (gabapentin). (*In re Gabapentin Patent Litig.*, MDL No. 1384

(D.N.J.); *Pfizer Inc. v. Apotex Corp.*, 01-CV-611 (D.N.J.); *Pfizer Inc. v. Apotex Corp.*, 00-CV-4398 (N.D. Ill.); *Warner-Lambert Co. v. Apotex Corp.*, 98-CV-4293 (N.D. Ill.); *Pfizer Inc. v. Pharm. Holdings Corp.*, 03-CV-740 (E.D. Pa.)); *Pfizer Inc. v. Geneva Pharms., Inc.*, 03-CV-1545 (D.N.J.); *Pfizer Inc. v. Ranbaxy Pharms., Inc.*, 03-CV-1824 (D.N.J.)).

56. Indeed, as recently as October 7, 2003, Pfizer stated that it intends to aggressively defend its intellectual property. *Found at* http://www.pfizer.com/are/news_releases.

Quinapril Hydrochloride Litigation

57. Pfizer has further demonstrated a willingness and intention to enforce the '450 patent against similarly-situated generic pharmaceutical companies that have filed an ANDA to market generic quinapril hydrochloride.

58. Pfizer has filed suit against one of TorPharm's competitors in *Warner-Lambert v. Teva Pharms. USA, Inc.*, 99-CV-0922 (D.N.J.), alleging infringement of the '450 patent. The district court in New Jersey recently granted Pfizer a summary judgment of infringement against Teva regarding the '450 patent.

59. Pfizer recently noted that the court decision on the '450 patent "affirms positions that [Pfizer] has taken with respect to the Accupril patent from the very beginning of the litigation." *Found at* http://www.pfizer.com/are/news_releases.

There Is A Substantial And Continuing Justiciable Controversy Between TorPharm And Pfizer Regarding Infringement Of The '450 Patent

60. By preparing and filing TorPharm's ANDA No. 76-240, TorPharm has substantially prepared to make, use, import, offer to sell, and sell quinapril hydrochloride tablets in the United States.

61. By submitting its ANDA No. 76-240 to engage in the commercial manufacture, use, offer for sale, sale, or importation of quinapril hydrochloride tablets before the expiration of

the '450 patent, as well as filing a paragraph IV certification to the '450 patent, TorPharm has committed an act that may be viewed as an artificial or technical act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2)(A).

62. By submitting the '450 patent to the FDA for listing in the Orange Book, Pfizer has indicated that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." *See* 21 U.S.C. § 355(b)(1). In other words, Pfizer necessarily maintains that an infringement claim on the '450 patent could be reasonably asserted against any generic quinapril applicant, including TorPharm.

63. Pfizer did not sue TorPharm for infringement of the '450 patent within forty-five (45) days of receipt of TorPharm's notice of paragraph IV certification. As such, a declaratory judgment action is available to TorPharm.

64. Pfizer has never communicated to TorPharm that TorPharm does not infringe or that Pfizer does not intend to bring a lawsuit against TorPharm for infringement of the '450 patent.

65. Pfizer has demonstrated a willingness and, further, an intention to enforce its '450 patent against similarly situated quinapril hydrochloride ANDA-filers. Also, just three weeks ago and after a favorable summary judgment award regarding the '450 patent, Pfizer made public representations that the decision is in line with Pfizer's beliefs regarding Accupril® (quinapril hydrochloride) and that Pfizer intends to continue aggressively defending its intellectual property.

66. Based upon, *inter alia*, Pfizer's listing of the '450 patent and implicit assertions that an infringement claim could be brought against any generic quinapril applicant; TorPharm's ANDA with a paragraph IV certification to the '450 patent and technical or artificial act of

infringement; TorPharm's intention to market its generic quinapril product before expiration of the '450 patent; Pfizer's failure to state that TorPharm does not infringe the '450 patent or covenant that it will not sue TorPharm for infringement of the '450 patent; Pfizer's suits against similarly situated third-parties concerning the '450 patent; Pfizer's public statements that it will continue to aggressively defend challenges to its intellectual property; Pfizer's (and its predecessors') pattern of aggressively enforcing its patents against TorPharm specifically and the generic pharmaceutical industry generally; and Pfizer's recent summary judgment of infringement regarding the '450 patent, TorPharm is under a reasonable apprehension that Pfizer will sue TorPharm alleging infringement of the '450 patent. Such a reasonable apprehension creates an actual controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

67. To avoid legal uncertainty, to protect its substantial investment, and to protect its anticipated future investments in its manufacturing process for TorPharm's quinapril hydrochloride tablets, TorPharm has instituted this action and is entitled to a declaration of the rights of the parties with respect to the '450 patent.

Declaratory Judgment Of Noninfringement

68. TorPharm asserts and realleges paragraphs 1 through 67 above as if fully set forth herein.

69. TorPharm has already committed what may constitute a technical or artificial act of infringement by submitting its ANDA with an accompanying paragraph IV certification. TorPharm has also produced an allegedly infringing quinapril product and intends and is prepared to market that product before expiration of the '450 patent.

70. Pfizer has engaged, and continues to engage, in conduct giving rise to a reasonable and objective apprehension on TorPharm's part that TorPharm will face an infringement suit if it commences marketing of its generic quinapril product.

71. There is an actual, substantial, and continuing justiciable case and controversy between TorPharm and Pfizer regarding infringement of the '450 patent.

72. The manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent.

73. TorPharm is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent.

Prayer For Relief

WHEREFORE, TorPharm respectfully prays for judgment in its favor and against Pfizer:

(a) Declaring that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent; and

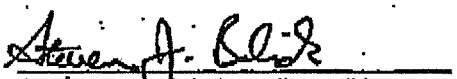
(b) Awarding TorPharm its reasonable attorneys' fees and costs of this action; and,

(c) Awarding TorPharm such other and further relief as the Court may deem just and proper.

Jury Demand

The Plaintiffs, TorPharm, Inc., Apotex Corp., and Apotex, Inc., hereby demand a trial by jury on all issues so triable.

ASHBY & GEDDES



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Dated: October 29, 2003
134500.1

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs	)	
v.	)	C.A. No. 07-792 (GMS)
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

ANSWER OF APOTEX INC. AND APOTEX CORP.
TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants, Apotex Inc. and Apotex Corp., Answer the Complaint of Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 1 of the Complaint, and on that basis deny such averments.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 2 of the Complaint, and on that basis deny such averments.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufacturers numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; that Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings, Inc. and that Apotex, Inc. manufacturers numerous drugs that are sold and used in this judicial district. Apotex, Inc. and Apotex Corp. deny that Apotex Pharmaceutical Holdings, Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc. Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 with respect to whether its products are sold and used "throughout the United States", and on that basis deny such averments.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, but deny that Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs' Complaint purports to bring this action for the alleged infringement of United States Patent No. 4,661,491 ("the '491 patent") and that a copy of the '491 patent appears to be attached to the Complaint as Exhibit A. Apotex, Inc. and Apotex Corp. also admits that Plaintiffs purport to bring this action based on the Patent Laws of the United States, 35 U.S.C. §1 et seq.

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Apotex, Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortuous action of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff Sanofi-Aventis U.S., which manufacturers numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Apotex Corp. admits that this Court has personal jurisdiction over it in this District for the purposes of this action. For purposes of this action, Apotex, Inc. does not contest the Court's personal jurisdiction over it. Apotex, Inc. and Apotex Corp. deny the averments against them to the extent they assert Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent

infringement or that Plaintiff Sanofi-Aventis U.S. has been injured or otherwise harmed through any alleged tortious acts of Defendants. As to the remaining averments, Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to their truth or falsity and on that basis deny such averments.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia,* its systematic and continuous contacts with Delaware, including through its sister corporation and agent Apotex Corp.

ANSWER: For purposes of this action, Apotex, Inc. does not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction asserted in this paragraph, including that Apotex Corp. is Apotex, Inc.'s "sister corporation and agent."

9. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Inc. is a Delaware corporation.

ANSWER: Apotex Corp. does not dispute the Court's jurisdiction over it.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Apotex, Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action, but believe that the Southern District of Florida is a more convenient venue and that this case should be transferred there and joined with the copending civil action no. 07 C 61800 (S.D. Fla.), in which Apotex, Inc. and Apotex Corp. already have filed answers and counterclaims.

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended

release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

ANSWER: Apotex, Inc. and Apotex Corp. admit that the '491 patent issued on April 28, 1987, but deny that this patent was duly and legally issued. Apotex, Inc. and Apotex Corp. admit that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® and that Sanofi-Aventis U.S. is listed as the Applicant for NDA No. 21-287. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of Paragraph 11 of the Complaint, and on that basis deny such averments.

Acts Giving Rise to this Action
Infringement of the '491 Patent by Defendants

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10mg strength. Defendants admit that Apotex, Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. The remaining averments of this paragraph are denied.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j) (2) (A) (vii) (IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j) (2) (A) (vii) (IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. provided Plaintiffs with notice of its ANDA No. 79-013, that such notice satisfied all statutory and regulatory requirements and that Plaintiffs received notice on or about October 25, 2007. The remaining averments of this paragraph are denied.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j) (2) (A) (vii) (IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 14 of the Complaint.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 15 of the Complaint.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j) (2) (A) (vii) (IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 16 of the Complaint.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j) (2) (A) (vii) (IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 17 of the Complaint.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 18 of the Complaint.

GENERAL DENIAL

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.

DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following defenses to the Complaint:

FIRST DEFENSE

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of Apotex Inc.'s ANDA No. 79-013 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '491 patent, either literally or under the doctrine of equivalents.

SECOND DEFENSE

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD DEFENSE

Plaintiffs have failed to state a claim on which relief can be granted.

Defendants reserve their right to assert any and all additional defenses and counterclaims that discovery may reveal.

COUNTERCLAIMS

Apotex Inc. and Apotex Corp., (collectively "counterplaintiffs") for their Counterclaims against Sanofi-Aventis ("Sanofi-Aventis") and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") (the counter-defendants will be referred to herein collectively as "Sanofi"), allege as follows:

The Parties

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Ontario, Canada M9L 1 T9.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida 33326.

3. Sanofi-Aventis U.S. has alleged that it is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

4. Sanofi-Aventis has alleged that it is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

Jurisdiction and Venue

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food,

Drug and Cosmetic Act, 21 U.S.C. §301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA").

6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 (a).

7. The Court has personal jurisdiction over Sanofi because Sanofi has availed themselves to the rights and privileges of this forum by suing counterplaintiffs in this District and because Apotex Corp. is incorporated in this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400 (b).

Patents-in-Suit

9. On or about April 28, 1987, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,661,491 ("the '491 patent"), entitled "ALFUZOSINE COMPOSITIONS AND USE" to Francois Regnier.

10. Sanofi-Aventis purports to own and to have the right to enforce the '491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940 ("the '940 patent") entitled "TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE" to Lauretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau and Clemence Rauch-Desanti.

12. Sanofi-Aventis purports to own an interest in'940 patent and on information and belief has an exclusive license and the right to unilaterally bring and proceed with lawsuits to enforce the '940 patent in its own name.

13. Sanofi-Aventis U.S. is identified as the owner of New Drug Application No. 21-287 on Uroxatral brand alfuzosin hydrochloride extended release tablets. The '491 patent and the '940 patent are listed in the Orange Book for Uroxatral.

14. Sanofi has attempted to enforce the '940 patent against multiple other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets.

15. Apotex has submitted an abbreviated new drug application (ANDA) No. 79-013 to the FDA. Apotex Inc.'s ANDA seeks FDA approval for the commercial use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet.

16. Pursuant to 21 U.S.C. § 355(j) (2) (B) (ii) and 21 C.F.R. § 314.95, Apotex, Inc. has certified to Sanofi that the '491 patent and the '940 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use of sale of the new drug for which ANDA 79-013 is submitted.

17. On or about August 14, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent.

18. On or about October 15, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

19. On or about December 10, 2007, Sanofi sued Apotex Inc and Apotex Corp in this District alleging infringement of the '491 patent under 35 U.S.C. § 271 (e)(2)(A).

20. Counterplaintiffs have a reasonable apprehension of being sued by Sanofi for alleged infringement of the '940 patent because, *inter alia*, Apotex, Inc. has served Sanofi with its Paragraph IV certification letter asserting that the'940 patent was not infringed, Sanofi has sued more than ten other ANDA holders seeking to market alfuzosin hydrochloride extended release tablets for alleged infringement of the '940 patent, and Sanofi already has sued counterplaintiffs for infringement of the '491 patent in this court.

21. As a result of Sanofi's actions in listing of the '491 and '940 patents in the Orange Book and in suing counterplaintiffs for infringement of the '491 patent, counterplaintiffs are presently prevented from selling alfuzosin hydrochloride extended release tablets and are being injured as a result. Counterplaintiffs seek patent certainty with respect to the '491 and '940 patents and certainty regarding the legal rights relating to Apotex, Inc.'s ANDA through a judicial declaration that the '491 and '940 patents are not infringed by the alfuzosin hydrochloride extended release tablets identified in Apotex, Inc.'s ANDA, or that the patents are invalid.

22. A real, actual, and justiciable controversy exists between counterplaintiffs and Sanofi regarding the invalidity of the '491 and '940 patents and counterplaintiffs' non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I
(Declaration of Non-Infringement of the '491 Patent)

23. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-22.

24. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s

ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

25. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

COUNT II
(Declaration of Invalidity of the '491 Patent)

26. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-25.

27. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

28. Counterplaintiffs are entitled to a declaration that the claims of the '491 patent are invalid.

COUNT III
(Declaration of Non-infringement of the '940 Patent)

29. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-28.

30. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

31. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets,

10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

COUNT IV
(Declaration of Invalidity of the '940 Patent)

32. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-31.

33. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Counterplaintiffs are entitled to a declaration that the claims of the '940 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

(a) Declaring that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;

(b) Declaring that the claims of the '491 patent are invalid;

(c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;

(d) Declaring that the claims of the '940 patent are invalid;

(e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding counterplaintiffs their attorneys' fees, costs, and expenses in this action; and

(f) Awarding counterplaintiffs any further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Apotex, Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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Dated: January 2, 2008
840396 / 32533

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 2, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 2, 2008, I have Electronically Mailed the document to the following person(s)

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840408 / 32533

EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD. and ALLERGAN, INC., Plaintiffs,	)	
v.	)	C.A. No. 07-779-***-LPS
APOTEX, INC., APOTEX CORP. and APOTEX PHARMACHEM INDIA, PVT, LTD., Defendants.	)	

DEFENDANTS APOTEX, INC. AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIM TO PLAINTIFF'S COMPLAINT

Defendants Apotex, Inc. and Apotex Corp. (collectively "Apotex") for their Answer, Affirmative Defenses and Counterclaim to Plaintiffs' SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD.,and ALLERGAN, INC., ("Plaintiffs" or "SENJU") Complaint state as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Letters Patent No. 6,333,045 ('045 Patent) under 35 U.S.C. §271(e) (2).

ANSWER:

Apotex admits that this action purports to be one for infringement of United States Patent No. 6,333,045 ("the '045 patent") under 35 U.S.C. §271(e) (2).

THE PARTIES

2. Plaintiff Senju is a corporation organized under the laws of Japan having a place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

ANSWER:

Admitted on information and belief.

3. Plaintiff Kyorin is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chonie, Chiyoda-ku, Tokyo 101-8311 Japan.

ANSWER:

Admitted on information and belief.

4. Plaintiff Allergan is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California, 92612.

ANSWER:

Admitted on information and belief.

5. On information and belief, defendant Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

ANSWER:

Admitted.

6. On information and belief, defendant Apotex Corp. offers for sale and sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

ANSWER:

Apotex admits that Apotex Corp. offers for sale and sells drug products in the United States, including this judicial district, manufactured and supplied by Apotex, Inc. All other allegations of paragraph 6 are denied.

7. On information and belief, defendant Apotex Inc. is a corporation organized under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

ANSWER:

Admitted.

8. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

ANSWER:

Apotex admits that Apotex, Inc. manufactures numerous drug products for sale and use in the United States including this judicial district, but denies all other allegations set forth in paragraph 8.

9. On information and belief, Apotex, Inc. has formulated and sold to Apotex Corp. a gatifloxacin ophthalmic solution 0.3% knowing that the solution's only use was to prepare and file an Abbreviated New Drug Application ("ANDA") with the FDA. Plaintiffs reserve the right to amend the complaint to substitute a different party for Apotex, Inc. if, through discovery, Plaintiffs discover that a company other than Apotex Inc, is formulating and selling the gatifloxacin ophthalmic solution 0.3% to Apotex Corp.

ANSWER:

Apotex Corp. denies the allegations contained in paragraph 9.

10. On information and belief, defendant Apotex India is a corporation organized under the laws of India and having a place of business at Site 1 A, Bommasandra Industrial Area, 4th Phase, Jigani Link Road, Bangalore - 560 099 India.

ANSWER:

This paragraph is not addressed to Apotex and does not require a response from Apotex. To the extent one is required, Apotex admits the allegations on information and belief.

11. On information and belief, defendant Apotex India manufactures generic drugs for sale and use throughout the United States, including this judicial district.

ANSWER:

The allegations of paragraph 11 are not directed at and do not require a response from Apotex. To the extent a response is required, Apotex denies knowledge or information sufficient to form a belief as to those allegations and therefore denies them.

12. On information and belief, Apotex India filed a Drug Master File for the gatifloxacin active pharmaceutical ingredient (API) and has sold gatifloxacin API to Apotex Corp. knowing that its only use was to prepare gatifloxacin ophthalmic solution 0.3% for use in the preparation and filing of an ANDA with the intent to market the solution in the United States before the expiration of the '045 patent.

ANSWER:

Apotex admits on information and belief that Apotex India filed a Drug Master File for gatifloxacin API but denies all other allegations of paragraph 12.

13. On information and belief, the acts of Apotex Corp. complained of herein were done with the authorization of, with the cooperation, participation, and assistance of, and in part, for the benefit of Apotex, Inc. and Apotex India.

ANSWER:

The averments of paragraph 13 are sufficiently vague and ambiguous that Apotex denies information or knowledge sufficient to form a belief as to those averments and therefore denies and demands strict proof thereof.

JURISDICTION AND VENUE

14. This action arises under 35 U.S.C. Section 1, *et seq.* This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

Admitted.

15. This court has personal jurisdiction over the defendants.

ANSWER:

Apotex admits that Apotex Corp. and Apotex, Inc. consent to jurisdiction in this Court, but otherwise denies knowledge or information sufficient to form a belief as to the remaining defendant.

16. Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b)

ANSWER:

Admitted as to Apotex, which otherwise denies knowledge or information sufficient to form a belief as to the remaining defendant.

BACKGROUND

17. The '045 patent, entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin," issued on December 25, 2001. A copy of the '045 patent is attached to this complaint as Exhibit A.

ANSWER:

Apotex admits that what purports to be a copy of the '045 patent is attached to the Complaint as Exhibit A which is entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin" and lists an issue date of December 25, 2001. Apotex denies any remaining allegations contained in paragraph 16.

18. Senju and Kyorin jointly own the entire right and interest in the '045 patent.

ANSWER:

Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 18 and therefore denies them.

19. Allergan is the exclusive licensee of the '045 patent for ophthalmic uses.

ANSWER:

Apotex denies knowledge or information sufficient to form a belief as to the allegation in paragraph 19 and therefore denies it.

20. Allergan is the holder of approved New Drug Application ("NDA") No. 02-1493 that covers Zymar® which is a 0.3% solution of gatifloxacin.

ANSWER:

Apotex admits that the FDA lists Allergan as the holder of approved New Drug Application ("NDA") No. 02-1493 on its website. Apotex is without knowledge or information sufficient to form a belief as to the remaining allegations contained in paragraph 20.

21. In conjunction with NDA No. 02-1493, Allergan has listed the '045 patent (and others) in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") maintained by the U.S. Food and Drug and Administration ("FDA"). Listing patents in the Orange Book obligates drug companies seeking approval to market a generic

version of listed drug before the expiration of a listed patent to provide notice to the owner of the listed patent(s) and to the NDA holder with certain exceptions which do not apply to this case.

ANSWER:

Apotex admits on information and belief that Allergan has listed the '045 patent in the Orange Book. The remaining allegations of paragraph 21 are conclusions of law or are vague and do not require a response and therefore are denied.

22. On information and belief, on July 13, 2007, Apotex India filed a Drug Master File for the gatifloxacin API.

ANSWER:

Apotex admits the allegations of paragraph 22 on information and belief.

23. On information and belief, on July 19, 2007, Apotex Corp. filed ANDA No. 79-084 for gatifloxacin ophthalmic solution 0.3% with a Paragraph IV certification.

ANSWER:

Apotex admits that Apotex Corp. is holder of ANDA No. 79-084 for gatifloxacin ophthalmic solution 0.3%, which contains a Paragraph IV certification. Apotex Corp. denies all remaining allegations contained in paragraph 23.

24. In a letter dated October 17, 2007, Apotex Corp. advised Senju, Kyorin and Allergan that it had filed ANDA No. 79-084 for gatifloxacin ophthalmic solution 0.3% which is the subject of Allergan's NDA.

ANSWER:

Apotex admits that Apotex Corp. transmitted a letter dated October 17, 2007 to Senju, Kyorin and Allergan. Apotex refers Plaintiffs to the referenced letter for its explicit

terms. To the extent Plaintiffs' characterizations differ from the actual terms of the referenced letter, they are denied.

25. The October 17, 2007 letter purports to advise Plaintiffs pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. §314.95 that Apotex Corp.'s ANDA had been filed with a Paragraph IV certification to obtain approval to market a gatifloxacin ophthalmic solution 0.3%

before the expiration of either the '045 patent or U.S. Patent 5,880,283 (the '283 patent).

ANSWER:

Apotex admits that Apotex Corp. transmitted a letter dated October 17, 2007 and refers Plaintiffs to the referenced letter for its explicit terms. To the extent Plaintiffs' characterizations differ from the actual terms of the referenced letter, they are denied..

26. Apotex Corp. in its detailed statement submitted with the October 17, 2007, letter ("Apotex Corp.'s statement") asserts only that the '283 patent will not be infringed.

ANSWER:

Apotex admits that Apotex Corp. transmitted a letter dated October 17, 2007 to Senju, Kyorin and Allergan containing a detailed statement. Apotex refers Plaintiffs to Apotex Corp.'s statement for its explicit terms. To the extent Plaintiffs' characterizations differ from the actual terms of Apotex Corp.'s statement they are denied.

27. Currently Plaintiffs have insufficient information upon which to form a belief regarding the infringement of the '283 patent. Plaintiffs reserve the right to amend this complaint or to file a new complaint should evidence become available tending to demonstrate that one or more of the defendants infringe the '283 patent.

ANSWER:

Apotex admits that Plaintiffs' Complaint does not assert a claim for infringement of the '283 patent. Apotex denies all remaining allegations contained within paragraph 27.

28. Apotex Corp.'s statement does not assert that its gatifloxacin ophthalmic solution 0.3% product does not infringe claims 1 -- 3 and 6 -- 9 of the '045 patent.

ANSWER:

Apotex denies all allegations contained in paragraph 28.

29. On information and belief, Apotex Corp. admits that its gatifloxacin ophthalmic solution 0.3% product infringes claims 1 -- 3 and 6 - 9 of the '045 patent if valid.

ANSWER:

Apotex denies all allegations contained in paragraph 29.

30. The claims of the '045 patent have a statutory presumption of validity.

ANSWER:

The allegations of paragraph 30 are conclusions of law to which no response or pleading is required. Apotex denies that the '045 patent is valid.

COUNT I

Infringement of the '045 Patent Under 35 U.S.C. § 271(e)(2)

31. Paragraphs 1 - 30 are incorporated herein as set forth above.

ANSWER:

Apotex repeats and reasserts its responses set forth in Paragraphs 1 - 30 as if set forth herein in full.

32. Apotex Corp.'s submission of ANDA No. 79-084 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of

gatifloxacin ophthalmic solution 0.3% in the United States before the expiration of the '045 patent was an act of infringement under 35 U.S.C. § 271 (e) (2) (A) of the '045 patent.

ANSWER:

The averments of paragraph 32 set forth conclusions of law to which no response or pleading is required. To the extent that such averments require a response, those averments are denied.

33. Apotex Corp.'s commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution 0.3% prior to the expiration of the '045 patent and after the filing of the ANDA will be an act of patent infringement of the '045 patent claims 1 -3 and 6 - 9. 35 U.S.C. § 271(a).

ANSWER:

Apotex denies all allegations contained in paragraph 33.

34. Apotex, Inc. and Apotex India are jointly and severally liable for Apotex Corp.'s infringement of the '045 patent. On information and belief, Apotex, Inc. and Apotex India participated in, contributed to, aided, abetted, and/or induced Apotex Corp.'s submission of ANDA No. 79-084 to the FDA.

ANSWER:

Apotex denies all allegations contained in paragraph 34.

35. Apotex, Inc.'s and Apotex India's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 79-084 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '045 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Apotex, Inc.'s or Apotex India's offer for sale of the proposed gatifloxacin ophthalmic solution 0.3% would infringe the '045 patent.

ANSWER:

Apotex denies all allegations contained in paragraph 35.

36. On information and belief, Defendants were aware of the existence of the '045 patent and were aware that the filing of ANDA No. 79-084 and certification with respect to the '045 patent constituted infringement of that patent. This is an exceptional case.

ANSWER:

Apotex admits that ANDA No. 79-084 contained a Paragraph IV certification with respect to the '045 patent when filed. Apotex denies all remaining allegations contained in paragraph 36.

COUNTS II AND III

Concurrent with this Answer, Apotex, Inc. and Apotex Corp. have filed a Motion to Dismiss Counts II and III of Plaintiffs' Complaint pursuant to Fed. R. Civ. P. 12(b)(6). Apotex will provide an answer to Count II and/or Count III at such time as required pursuant to the Federal Rules of Civil Procedure, or as may be ordered by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed the '045 patent;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 79-084 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier that the expiration date of the '045 patent or any extension thereof;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active

concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '045 patent for the full term thereof;

D. A preliminary injunction restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement, inducing infringement, or contributory infringement of the '045 patent

for the full term thereof until such time as the Court issues a final decision on the merits;

E. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

ANSWER:

Apotex specifically denies that Plaintiffs are entitled to the general or specific relief requested against Apotex, or to any relief whatsoever, and prays for judgment in favor of Apotex dismissing this action with prejudice, and awarding Apotex its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Apotex, Inc. and Apotex Corp. (collectively "Apotex") aver and assert the following Affirmative Defenses to Plaintiffs', Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd. and Allergan, Inc.'s Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 6,333,045)

The manufacture, use, sale, offer to sell or importation into the United States of Apotex's proposed gatifloxacin ophthalmic solution that is the subject matter of ANDA No. 79-084 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 6,333,045 (the "045 patent") either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 6,333,045)

Upon information and belief, the claims of the '045 patent are invalid and/or unenforceable for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112, and/or 37 CFR § 1.56.

COUNTERCLAIMS

1. Counterclaimant Apotex Corp. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

2. Counterclaimant Apotex, Inc. is a corporation organized under the laws of Canada, and its principal place of business is located at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

3. Upon information and belief, Counterclaim Defendant Senju Pharmaceutical Co., Ltd. ("Senju") is a corporation organized and existing under the laws of Japan having a place of business at 2-5-8, Hirano-Machi, Chuo-ku, Osaka 541-0046, Japan.

4. Upon information and belief, Counterclaim Defendant Kyorin Pharmaceutical Co., Ltd. ("Kyorin") is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311, Japan.

5. Upon information and belief, Counterclaim Defendant Allergan, Inc. ("Allergan") is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California,

92612. As a consequence of Plaintiffs/Counterclaim Defendants' complaint against Apotex Corp. there is now an existing, continuing actual controversy between Senju, Kyorin and Allergan and Apotex Corp., regarding the alleged infringement, validity and enforceability of U.S. Patent Nos. 6,333,045, ("the '045 patent") and 5,880,283 ("the '283 patent").

6. This Court has jurisdiction over the subject matter of these counterclaims pursuant to §§ 1331 and 1338 (a) of Title 28 of the U.S. Code because they involve substantial claims arising out of the United States Patent Act, 35 U.S.C. § 1, *et. seq.*

7. This Court may declare the rights and legal relation for the parties pursuant to §§ 2201 and 2202 of Title 28 of the U.S. Code and § 271 (e)(5) of Title 35 of the U.S. Code because Apotex Corp.'s counterclaims present an actual controversy within the Court's jurisdiction that the patents asserted by Plaintiffs/Counterclaim Defendants against Defendant/Counterclaim Plaintiff, Apotex Corp. are not infringed and/or are invalid.

8. Venue for these counterclaims is proper within this District in which Plaintiffs/Counterclaim Defendants' Complaint is pending.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '045 PATENT

9. The manufacture, use, sale, offer to sell or importation into the United States of Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 79-084 would not and will not directly, indirectly, contributorily and/or by

inducement, infringe any validly construed claim of the '045 patent either literally or under the doctrine of equivalents.

COUNT II
DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '045 PATENT

10. Upon information and belief, the claims of the '045 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112.

COUNT III
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '283 PATENT

11. The manufacture, use, sale, offer to sell or importation into the United States of Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 79-084 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '283 patent either literally or under the doctrine of equivalents.

COUNT IV
DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '283 PATENT

12. Upon information and belief, the claims of the '283 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Apotex, Inc. and Apotex Corp, respectfully request the Court to enter judgment against counterclaim defendants Senju, Kyorin, and Allergan as follows:

A. Declaring that Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 79-084 would not and will not directly, indirectly,

contributorily and/or by inducement, infringe any validly construed claim of the '045 patent either literally or under the doctrine of equivalents.

B. Declaring that Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 79-084 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '283 patent either literally or under the doctrine of equivalents.

C. Declaring that U.S. Patent No. 6,333,045 is invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, 102, 103, and/or 112.

D. Declaring that U.S. Patent No. 5,880,283 is invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, 102, 103, and/or 112.

E. Awarding Apotex Corp. its reasonable costs and attorneys fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and

F. Awarding all such other and further relief as this Court may deem just and proper.

Dated: January 22, 2007

Respectfully Submitted,

/s/Francis J. Murphy

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CERTIFICATE OF SERVICE

The undersigned on oath states that foregoing **DEFENDANTS APOTEX, INC. AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIM TO PLAINTIFF'S COMPLAINT** was served on the following counsel by electronic filing with the Court's ECF system and by placing a true and correct copy in the U.S. Mail on this 22nd day of January, 2008.

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149452

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 07-278-GMS
	)	
APOTEX, INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S ANSWER, DEFENSES, AND COUNTERCLAIMS.

Defendants Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the Complaint of Allergan, Inc. ("Allergan" or "Plaintiff"), state and allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent") under 35 U.S.C. §271(e)(2).

ANSWER: Apotex Inc. and Apotex Corp. admit that the Complaint alleges infringement of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent") under 35 U.S.C. §271(e)(2); otherwise denied.

THE PARTIES

2. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

3. On information and belief, defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

ANSWER: Admitted that Apotex Inc. is a Canadian corporation with a place of business in Ontario Canada, all other allegations are denied.

4. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

ANSWER: Admitted.

5. On information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

ANSWER: Admitted.

6. On information and belief, Apotex Corp. sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. sells generic drug products manufactured by Apotex Inc. throughout the United States, including this judicial district; otherwise denied.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq. This Court has subject matter jurisdiction over the action under 28 U.S.C. §1331 and 1338.

ANSWER: Apotex Inc. and Apotex Corp. admit that Allergan purports to bring this action under the patent laws of the United States, Title 35, Section 1, et seq. Apotex Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the action under 28 U.S.C. §1331 and 1338(a). Except where specifically admitted, the allegations in this paragraph are otherwise denied.

8. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants.

ANSWER: Admitted that the Court has personal jurisdiction over Apotex Inc. and Apotex Corp.; otherwise denied.

9. Venue is proper in this Court under 28 U.S.C. §1391 and 1400(b).

ANSWER: Admitted.

BACKGROUND

10. The '078 patent, entitled "Aqueous Ophthalmic Formulations and Methods for Preserving Same," issued to Anthony Dziabo and Paul Ripley on June 13, 1995. A copy of the '078 patent is attached to this complaint as Exhibit A.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the cover page of the '078 patent includes a title of "Aqueous Ophthalmic Formulations and Methods for Preserving Same," lists the inventors as Anthony Dziabo and Paul Ripley, and lists an issue date of June 13, 1995. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

11. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '078 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Allergan is identified as assignee on the cover page of the '078 patent. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

12. The '873 patent, entitled "Compositions Containing Therapeutically Active Components Having Enhanced Solubility," issued to Orest Olejnik and Edward D.S. Kerslake on May 13, 2003. A copy of the '873 patent is attached to this complaint as Exhibit B.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the cover page of the '873 patent includes a title of "Compositions Containing Therapeutically Active Components Having Enhanced Solubility," lists the inventors as Orest Olejnik and Edward D.S. Kerslake, and lists an issue date of May 13, 2003. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

13. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '873 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Allergan is identified as assignee on the cover page of the '873 patent. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

14. The '210 patent, entitled "Compositions Containing α-2-Adrenergic Agonist Components," issued to Orest Olejnik and Edward D.S. Kerslake on September 30, 2003. A copy of the '210 patent is attached to this complaint as Exhibit C.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the cover page of the '210 patent includes a title of " Compositions Containing α-2-Adrenergic

Agonist Components," lists the inventors as Orest Olejnik and Edward D.S. Kerslake, and lists an issue date of September 30, 2003. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

15. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '210 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Allergan is identified as assignee on the cover page of the '210 patent. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

16. The '337 patent, entitled "Compositions Containing Alpha-2-Adrenergic Agonist Components," issued to Orest Olejnik and Edward D.S. Kerslake on January 6, 2004. A copy of the '337 patent is attached to this complaint as Exhibit D.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the cover page of the '337 patent includes a title of " Compositions Containing Alpha-2-Adrenergic Agonist Components," lists the inventors as Orest Olejnik and Edward D.S. Kerslake, and lists an issue date of January 6, 2004. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

17. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '337 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Allergan is identified as assignee on the cover page of the '337 patent. Defendants Apotex Inc. and

Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

18. The '834 patent, entitled "Compositions Containing Alpha-2-Adrenergic Agonist Components," issued to Orest Olejnik and Edward D.S. Kerslake on November 4, 2003. A copy of the '834 patent is attached to this complaint as Exhibit E.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the cover page of the '834 patent includes a title of " Compositions Containing Alpha-2-Adrenergic Agonist Components," lists the inventors as Orest Olejnik and Edward D.S. Kerslake, and lists an issue date of November 4, 2003. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

19. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '834 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Allergan is identified as assignee on the cover page of the '834 patent. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

20. Allergan is the holder of approved New Drug Applications ("NDAs") No. 21-262 and 21-770 for 0.15% and 0.10% brimonidine tartrate ophthalmic solutions, respectively, sold under the ALPHAGAN® P trademark.

ANSWER: Admitted.

21. In conjunction with those NDAs, Allergan has listed with the FDA five patents (the "Listed Patents") that cover various aspects of the approved formulations of ALPHAGAN® P 0.15% and 0.10%. The Listed Patents are the '078, '873, '210, '337 and '834 patents.

ANSWER: Admitted that in conjunction with NDA No. 21-262 and 21-770, Allergan listed the '078, '873, '210, '337 and '834 patents. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

22. ALPHAGAN® P 0.15% and 0.10% are covered by at least one claim of each of the Listed Patents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

23. On April 30,2007, Allergan received a letter, dated April 26,2007, signed on behalf of Apotex, Inc. The letter stated that Apotex had filed Abbreviated New Drug Application Nos. 78-479 and 78-480 ("ANDAs") with the United States Food and Drug Administration ("FDA") under section 505('j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market generic versions of Allergan's ALPHAGAN® P products, both the 0.15% and 0.10% formulations, before the expiration of the Listed Patents.

ANSWER: Admitted that Apotex Inc. sent a letter to Allegan on April 26, 2007; that the letter stated that Apotex Inc. had submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480, before the expiration of the listed patents; otherwise denied.

24. The purpose of the April 26, 2007 letter was to notify Allergan that Apotex had filed a certification with the FDA under 21 C.F.R. § 314.50(i)(l)(i)(A)(4) ("Paragraph IV

certification") in conjunction with its ANDAs. The letter alleged: (1) that the Listed Patents were invalid or unenforceable and (2) that, even if valid and enforceable, some claims of the Listed Patents would not be infringed by Apotex's generic versions of Allergan's ALPHAGAN® P products.

ANSWER: Admitted that the April 26, 2007 letter provided Allergan with notice that Apotex Inc. had filed a Paragraph IV certification with the FDA in conjunction with ANDA application nos. 78-479 and 78-480, admitted that the April 26, 2007 letter stated that the listed patents are invalid, unenforceable, and/or will not be infringed by Apotex's manufacture, use, or sale of the Apotex Brimonidine Products, otherwise denied.

25. In filing its ANDAs, Apotex has requested the FDA's approval to market generic versions of Allergan's ALPHAGAN® P products throughout the United States, including Delaware.

ANSWER: Admitted that Apotex Inc. had submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480, throughout the United States, including Delaware; otherwise denied.

26. On information and belief, following FDA approval of its ANDAs, Apotex, Inc., through Apotex Corp., will sell the approved generic versions of Allergan's ALPHAGAN® P products throughout the United States, including Delaware.

ANSWER: Admitted that if the FDA approves Apotex Inc.'s ANDA applications, it will seek to sell its approved Brimonidine Tartrate products throughout

the United States, and that it would be expected that such approved products would be sold by Apotex Inc., otherwise denied.

COUNT I

(Infringement of the '078 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

27. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

28. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.15% as defined in ANDA application 78-479. The remainder of the allegations are denied.

29. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078 patent.

ANSWER: Denied.

COUNT II

(Infringement of the '873 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

30. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

31. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271(e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.15% as defined in ANDA application 78-479. The remainder of the allegations are denied.

32. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '873 patent.

ANSWER: Denied.

COUNT III

(Infringement of the '210 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

33. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

34. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1 5% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.15% as defined in ANDA application 78-479. The remainder of the allegations are denied.

35. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '210 patent.

ANSWER: Denied.

COUNT IV

(Infringement of the '337 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

36. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

37. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA)

under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.15% as defined in ANDA applications 78-479. The remainder of the allegations are denied.

38. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '337 patent.

ANSWER: Denied.

COUNT V

(Infringement of the '834 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

39. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

40. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.15% as defined in ANDA application 78-479. The remainder of the allegations are denied.

41. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '834 patent.

ANSWER: Denied.

COUNT VI

(Infringement of the '078 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

42. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

43. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271(e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA application 78-480. The remainder of the allegations are denied.

44. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078 patent.

ANSWER: Denied.

COUNT VII

(Infringement of the '873 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

45. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

46. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. 9 271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA application 78-480. The remainder of the allegations are denied.

47. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '873 patent.

ANSWER: Denied.

COUNT VIII

(Infringement of the '210 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

48. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

49. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271(e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA application 78-480. The remainder of the allegations are denied.

50. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '210 patent.

ANSWER: Denied.

COUNT IX

(Infringement of the '337 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

51. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

52. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA)

under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA application 78-480. The remainder of the allegations are denied.

53. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '337 patent.

ANSWER: Denied.

COUNT X

(Infringement of the '834 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

54. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

55. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA application 78-480. The remainder of the allegations are denied.

56. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '834 patent.

ANSWER: Denied.

DEFENSES

FIRST DEFENSE: INVALIDITY

The '078, '873, '210, '337 and '834 patents are invalid and/or unenforceable on grounds specified in United States Code, Title 35, including the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

SECOND DEFENSE: FAILURE TO JOIN INVENTORS

The '078 patent is invalid under 35 U.S.C. §116 and §256 for failure to join all proper inventors.

THIRD DEFENSE: UNENFORCEABILITY OF '078 PATENT

For the reasons set forth in more detail in Count III of the Counterclaims below, the '078 patent is unenforceable due to inequitable conduct.

FOURTH DEFENSE: UNENFORCEABILITY OF THE '210, '337 AND '834 PATENTS

For the reasons set forth in more detail in Count IV of the Counterclaims below, the '210, '337 and '834 patents are unenforceable due to inequitable conduct.

FIFTH DEFENSE: MISUSE

The '078 '210, '337 and '834 patents are invalid and were obtained improperly and by inequitable conduct. Knowing that the '078, '210, '337 and '834 patents are invalid and unenforceable, Allergan commenced this infringement action against Apotex Inc. and Apotex Corp. Allergan's efforts to enforce the '078, '210, '337 and '834 patents,

by suing for infringement and by maintaining the patents' listings in the Approved Drug Products With Therapeutic Equivalence Evaluation (also known as the "Orange Book"), constitute patent misuse.

SIXTH DEFENSE: NON-INFRINGEMENT

Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid claim of the '078, '873, '210, '337 and '834 patents. ANDA applications 78-479 and 78-480 do not infringe any valid claim of the '078, '873, '210, '337 and '834 patents. The proposed drug products for which approval is sought under ANDA applications 78-479 and 78-480 do not directly or indirectly infringe any valid claim of the '078, '873, '210, '337 and '834 patents.

COUNTERCLAIMS

Counterclaimants Apotex Inc. and Apotex Corp. for their counterclaim against counter-defendant Allergan Inc. ("Allergan") allege as follows:

PARTIES AND JURISDICTION

1. Apotex, Inc. is a Canadian corporation having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. On information and belief, Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

4. Allergan purports to own the entire right, title, and interest of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"),

6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent").

5. Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480.

6. Pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii) and 21 C.F.R. § 314.95, Apotex Inc. certified to Allergan that the '078, '873, '210, '337 and '834 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the proposed products for which ANDA applications 78-479 and 78-480 are submitted.

7. Allergan has commenced this civil action against Apotex Inc. and Apotex Corp. alleging patent infringement.

8. This case arises under the Constitution, laws, or treaties of the United States, viz., 35 U.S.C. §§ 1-376, which is an Act of Congress relating to patents, and 21 U.S.C. § 355, which provides subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. §271(e)(5).

9. Venue and personal jurisdiction are proper in this district because Allergan, inter alia, is subject to personal jurisdiction in this judicial district and has submitted itself to the jurisdiction of this Court.

10. A real, actual, and justiciable controversy exists between Apotex Inc. and Apotex Corp. on the one hand and Allergan on the other hand regarding the invalidity of

the '078, '873, '210, '337 and '834 patents and Apotex's non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 (2005).

COUNT I—DECLARATION OF INVALIDITY

11. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 10 as though set forth fully herein.

12. The '078, '873, '210, '337 and '834 patents are invalid and/or unenforceable on grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT II—DECLARATION OF INVALIDITY

13. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 10 as though set forth fully herein.

14. The '078 patent is invalid and/or unenforceable for failure to join all proper inventors as specified in 35 U.S.C. §116 and §256.

COUNT III--UNENFORCEABILITY OF '078 PATENT.

15. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 10 as though set forth fully herein.

16. On November 29, 1988, Bill McCarthy ("McCarthy"), as agent of Allergan, filed a patent application, eventually designated as U.S. Patent Application No. 07/277,791 (the '791 application). The '791 application was assigned to Allergan.

17. On January 25, 1998, Dziabo and Ripley declared that they were the original, first, and joint inventors of the subject matter claimed in the '791 application.

18. The '078 patent at issue in this lawsuit is a continuation in part of the '791 application, and also names Dziabo and Ripley as inventors.

19. On the same day that the '791 application was filed, November 29, 1988, McCarthy filed another patent application, eventually designated as U.S. Patent Application No. 07/277,790. The '790 application was assigned to Bio-Cide International Inc. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the '790 application names Bobby Danner as a sole inventor. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Bobby Danner declared, under penalty of perjury, himself to be the original, first, and sole inventor of the subject matter of the '790 application.

20. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the complete written descriptions and drawings of the '790 application and the '791 application as filed are nearly or exactly identical.

21. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that claims from the '790 application overlapped in scope with the '791 application. For example, claims of the '791 application were originally directed to solutions with "about 0.0002 to about 0.02 weight/volume percent stabilized chlorine dioxide as a preservative", while the '790 application claimed compositions with "at least 0.02 weight/volume percent stabilized chlorine dioxide as a disinfectant". There is no material difference in the '790 and '791 applications between

disinfection and preservation- both require the same compound do the same thing- kill contaminating microbes.

22. Claims in both the '790 and '791 applications covered exactly the same composition, that is, a solution having a concentration of stabilized chlorine dioxide of 0.02% weight/volume.

23. The fact that one or more persons other than the inventors named in the '791 application declared under penalty of perjury that they were the first, original inventors of a solution that was covered by the claims of the '791 application would have been material to the prosecution of the '791 application.

24. Allergan's agent McCarthy knew of the existence of both the '790 and '791 patent applications at the time they were both pending in the U.S. Patent Office. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that McCarthy knew of the overlap in scope of the claims of the '790 and '791 applications.

25. In connection with the '791 application, McCarthy never disclosed the '790 application to the United States Patent and Trademark Office.

26. On June 14, 1990, PCT application no. WO 90/06126 was published ('126 application). The published '126 application names Danner as the sole inventor. The published '126 application does not name either Dziabo or Ripley as an inventor. The published '126 application claims priority to the '790 application. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the '126 application includes the disclosure of the '790 application.

27. The application for the '078 patent was filed on May 2, 1991. The application for the '078 patent added new matter (e.g., "Example VIII (Comparative)") and claimed that new matter. The claims in the '078 patent that claim the new matter are entitled to a filing date no earlier than May 2, 1991.

28. The published '126 application is prior art to the '078 patent, and, in particular, is prior art to the claims of the '078 application that incorporate the new matter.

29. The published '126 application is material to the patentability of the '078 patent.

30. Neither Allergan, nor any applicant for the patent (as defined in 37 C.F.R. §1.56) disclosed the '790 application to the United States Patent and Trademark Office in connection with the application for the '078 patent.

31. Neither Allergan, nor any applicant for the patent (as defined in 37 C.F.R. §1.56) disclosed the published '126 application to the United States Patent and Trademark Office in connection with the application for the '078 patent.

32. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the foregoing misrepresentations and failure to disclose material prior art as set forth above were done with intent to mislead the United States Patent and Trademark Office.

33. The facts and circumstances set forth in this Count III constitute inequitable conduct on the part of the applicants, making the '078 patent unenforceable.

34. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for other and further circumstances constituting inequitable conduct by the applicants.

COUNT IV—INEQUITABLE CONDUCT

35. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 10 as though set forth fully herein.

36. The '834 and '337 patents both claim benefit to Application Serial No. 09/904,018 ("the Parent Application"), which matured into the '210 patent. The '834 patent matured from a continuation application of the Parent Application. The '337 patent matured from a divisional application of the Parent Application.

37. The '210, '834 and '337 patents contain the same specification (but for, understandably, differences in the claims and the section entitled "Cross Reference to Related Application").

38. The '210, '834 and '337 patents each claim therapeutically effective compositions.

39. The '210, '834 and '337 patents each name Orest Olejnik and Edward D.S. Kerslake as their inventors, who are, and/or were, employed by Allergan. The '210, '834 and '337 patents were each prosecuted by, or on behalf of, Allergan.

40. The '210, '834 and '337 patents were each examined by Rachel M. Bennett (hereinafter "Patent Examiner") for the United States Patent and Trademark Office (hereinafter "PTO").

41. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that during prosecution of the applications that matured into '210, '834 and '337 patents, each claim of each application was rejected as obvious under 35 U.S.C. § 103 over, inter. alia, the prior art Burke reference (United States Patent No. 5,215,991) and subsequently amended prior to issuance.

42. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Carlos A. Fisher, then an Allergan employee, was an attorney of record in connection with the prosecution of the applications that matured into the '210, '834 and '337 patents on behalf of Allergan after the claims in those applications were rejected over Burke.

43. The subject matter and prosecution of the '210, '834 and '337 patents are intertwined.

44. Allergan filed the Parent Application' which matured into the '210 patent, on July 10, 2001. That application, naming Orest Olejnik as the first inventor, claimed, *inter alia*, a composition comprising an alpha-2-adrenergic agonist in a therapeutically effective amount and a solubility enhancing component.

45. The application that matured into the '834 patent was filed on September 6, 2002. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the application was accompanied by a Preliminary Amendment that cancelled all pending claims and added claims to a composition containing, *inter alia*, "up to about 0.15% (wlv)" of brimonidine tartrate.

46. The application that matured into the '337 patent was filed on November 19, 2002, as a divisional application of the Parent Application, and was directed to

compositions containing an oxy-chloro preservative. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the application was accompanied by a Preliminary Amendment that cancelled all pending claims and added claims to a composition containing, inter alia, an alpha-2-adrenergic agonist in a therapeutically effective amount and an oxy-chloro preservative component.

47. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that: in the only Office Action during prosecution of the '834 patent, mailed on December 18, 2002, the Examiner rejected all pending claims as obvious over the Burke (U.S. Patent No. 5,215,991) in view of Beck et al. (U.S. Patent No. 6,358,935); that the Patent Examiner noted that Burke disclosed: (1) the claimed compound, 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, among its most preferred alpha-2-adrenergic compounds; (2) at a concentration from about 0.001% to about 1.0% (wlv), which encompassed the concentration range in the claims ("up to about 0.15% (wlv)"); and (3) that it was well known in the art how to determine the most efficacious ophthalmically acceptable dose (e.g., 0.15%); and that Beck was cited for its disclosure of a chlorite preservative component.

48. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that: in the only substantive Office Action during prosecution of the Parent Application (from which the '210 patent matured), mailed on January 15, 2003, the Patent Examiner rejected all pending claims as obvious over Burke in view of Remington's Pharmaceutical Sciences; that the wording of the Examiner's rejection with respect to Burke was identical to that in the '834 patent's prosecution except that, rather than noting Burke failed to disclose a chlorite preservative component,

the Examiner stated (erroneously) that Burke did not disclose the solubility enhancing agent to be carboxymethylcellulose (hereinafter "CMC") or the pH of its composition; and that Remington was cited for its disclosure of CMC.

49. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that on February 25, 2003, Allergan's attorney, Carlos A. Fisher, held a telephonic interview(s) with the Patent Examiner regarding the applications that matured into the '210 and '834 patents; that with respect to the pending claims in the Parent Application (which matured into the '210 patent), Allergan "explained the instant invention was an invention of selection" and "agreed to file a declaration showing unexpected results with regards to the anionic solubility enhancing agent [i.e. CMC];" and that with respect to the pending claims in the application that matured into the '834 patent, Allergan "explained the advantages of the composition comprising up to about 0.15% (wlv) of 5-bromo-6-(2-imidozolin-2-ylamino) quinozaline tartrate, wherein the composition has a pH of about 7.0 or greater were unexpected" and "agreed to file a declaration showing the unexpected results."

50. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that in the only Office Action during prosecution of the '337 patent, dated March 3, 2003 and mailed March 13, 2003, the Patent Examiner rejected all pending claims as obvious over Burke in view of Beck and that the wording of the Examiner's rejection with respect to Burke was largely identical to that in the applications that matured into the '210 and '834 patents, except that the Examiner stated (correctly) that Burke disclosed CMC. Beck was cited for its disclosure of a chlorite preservative component.

51. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that on March 12, 2003, Allergan submitted a "Reply to Office Action" in the Parent Application, and that the Reply, executed by Carlos Fisher, was accompanied by a "Declaration of Orest Olejnik, Ph.D." These documents were received by the Examiner's technology center at the PTO on March 24, 2003.

52. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the Reply to Office Action amended the pending claims to require, *inter alia*, that the claimed composition be a "therapeutically effective aqueous composition," comprising a 5- bromo-6-(2-imidozolin-2-ylamino) quinoxaline, or a salt or ester thereof, in a therapeutically effective amount and a "polyanionic" or "anionic" solubility enhancing component, and that the applicants also added several new dependent claims to compositions further comprising oxy-chloro preservative components. None of the claims contained a limitation regarding the adherence or adsorption of the compositions to cell surfaces.

53. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the March 12, 2003 Reply argued, in response to the outstanding obviousness rejection, that anionic solubility enhancing components such as CMC have "surprising" properties in the solubilization of brimonidine as compared to non-ionic or cationic polymers, stating, in part, that (p.7):

> In light of Dr. Olejnik's Declaration, the patent specification and the state of the art, the Applicants therefore submit that, alone or in combination with Remington, Burke contains no disclosure that would direct or motivate the person of ordinary skill in the art to select or want to select an anionic polymeric solubility enhancing component such as CMC from the list of optional viscous "vehicles" contained in the '991 patent.

54. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that in the accompanying Declaration of Orest Olejnik, Ph.D., Dr. Orest Olejnik, Allergan's Director of Pharmaceutical Development, stated, in part, that (776-8):

> Neither Burke nor Remington discloses that CMC would have any characteristics that would motivate a person or ordinary skill in the art to choose it over the other polymers in formulating a brimonidine solution.
>
> Unlike the other listed polymers (polyvinyl alcohol, povidone (polyvinylpyrrolidone), hydroxypropylcellulose, poloxamers, and hydroxyethylcellulose), CMC is anionic at pH7 or greater. The other listed polymers are non-ionic polymers. I have discovered as a result of work done and/or directed by me at Allergan that CMC possesses the surprising advantages of both increasing the solubility in solution, as shown in Table 1, and causing such solutions to have superior adherence to cell surfaces, including ocular surfaces such as the cornea. Polyvinyl alcohol was found not to possess both of these properties. Increased adherence of the CMC solution is particularly surprising given the fact that the corneal surface is negatively charged; one would expect less adherence in such a solution due to electrostatic repulsion, rather than increased adherence. . . .
>
> It is also my belief that brimonidine solutions made using the other "vehicles" mentioned in the Burke patent would not possess this surprising combination of advantages. Therefore, the disclosures of Burke and Remington's [sic] in so way would render the presently claimed compositions obvious to the worker of ordinary (or even extraordinary) skill in the art.

55. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that five days after mailing the Reply and Declaration in the Parent Application, Allergan mailed a "Reply to Office Action" in the prosecution of the application that matured into the '834 patent on March 17,2003. The March 17, 2003 Reply, executed by Carlos Fisher, was accompanied by a "Declaration of Amy

Batoosingh." These documents were received by the Patent Examiner's technology center on March 28, 2003.

56. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the March 17, 2003 Reply amended the pending claims to require, *inter alia*, that the claimed composition be a "therapeutically effective aqueous composition," and that Allergan also argued, with respect to the outstanding obviousness rejection, in part, that (p. 4-5):

> The present invention is the result of the surprising finding that increasing the pH of a brimonidine solution to a pH of greater than about 7.0 leads to similar efficacy at a 25% lower concentration (0.2% (wlv) to about 0.15% (wlv) or less) than is seen in a brimonidine solution at a pH of about 6.6-6.8. This appears to be due to the fact that at a pH closer to the pKa of brimonidine (which has a pKa of about 7.4) than pH 6.3-6.5, a larger proportion of the molecules are electrostatically neutral, and thus less lipophobic than the polarized molecule. As such, a greater amount of the active drug is able to enter the cornea of the eye at a given solution concentration; this effect counters the effects of decreased brimonidine solubility at the higher pH. See specification at e.g., paragraph bridging pages 1 and 2.
>
> However, it is particularly surprising that such a therapeutically effective dosage of brimonidine could be formulated in aqueous solution at a pH greater than about 7.0. Figure 1 of the present specification shows that brimonidine's solubility decreases precipitously at pH values above 7.0. The fact that a therapeutically effective dosage could be provided by a composition containing about 0.15% or less of brimonidine at such pH values is truly unexpected.
>
> * * *
>
> The advantages of this invention are manifest. Among others, it can be seen that although ophthalmic hypotensive therapeutic efficacy of the 0.15% solution is the same as for the 0.2% solution, the reduced concentration (and thus the reduced dosage) results in a lower potential for systemic side effects . . . A

> reduction in the dosage by 25% reduces the likelihood and severity of such side-effects.
>
> Thus, the present invention is drawn to surprising new therapeutic compositions comprising at least a 25% lower concentration of brimonidine than previous ophthalmic formulations, at pH closer both to the solubility limits of brimonidine, and to the pKa of the compound.

57. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that in the accompanying "Declaration of Amy Batoosingh," Amy Batoosingh, Allergan's Director of Ophthalmological Clinical Research, stated, in part, with respect to Katz *et al.*, 2002, *J. Glaucoma* 11:119, that (¶4):

> The conclusion reached as a result of the studies referenced in the Katz et al., article was that brimonidine 0.2% and brimonidine- Purite 0.15% showed comparable efficacy when each was used for treatment of ocular hypertension in glaucoma and/or ocular hypotensive human patients over a 12 month period of time, despite a significant reduction in the concentration of the active ingredient in the latter formulation.

58. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that on June 3, 2003, the Patent Examiner sent Allergan Notices of Allowance with respect to the claims of the '210 and '834 patents. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the '210 and '834 patents issued on September 30, 2003 and November 4, 2003, respectively, without further prosecution.

59. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan mailed its Reply to Office Action in the prosecution of the '337 patent on June 13, 2003, ten days after the Patent Examiner issued Notices of Allowance with respect to the '210 and '834 patents; that the Reply was

executed by Allergan's attorney, Carlos Fisher; that Allergan amended the pending claims to require, inter alia, that the claimed composition be "therapeutically effective" and contain an SEC other than a cyclodextrin; and that Allergan did not underline the requirement for "a solubility enhancing component" to indicate that it had been added in the amendment. Allergan also deleted the oxy-chloro limitation, which had been its purported reason for filing the divisional application. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that in response to the Examiner's obviousness rejection, Allergan argued, in part, that (p. 5):

> Applicants respectfully maintain that for all its discussion of possible formulations, nothing in Burke discloses or suggests the use of a solubility enhancing component in combination with an alpha adrenergic agonist. The present application, which also discloses the advantages of using such a component (such as greater flexibility with the concentration and pH at which such composition is formlated [sic: formulated)], is, to the Applicants' knowledge, the first reference to do so.

60. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that on October 4, 2003, the Patent Examiner sent Allergan a Notice of Allowance with respect to the '337 patent. The '337 patent issued on January 6, 2004 without further substantive prosecution.

61. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that at the time of filing, and during the prosecution of '210 patent application, Allergan made misrepresentations and/or omissions of material facts to the Patent Examiner and the United States Patent Office, including, but not limited to, the following:

a. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented and/or clearly implied that it had conducted comparative experiments with respect to solubility and/or adherence to cell surfaces. That representation and/or implication was false.

b. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented and/or clearly implied that polyvinyl alcohol, povidone, hydroxypropyl methyl cellulose, poloxamers, and/or hydroxyethyl cellulose were not solubility enhancing agents, not adhesive agents, and/or not solubility enhancing agents and not adhesive agents. The inventor(s), prosecuting attorney(s) and/or others substantively involved in the prosecution of the '210 patent believed that representation and/or implication to be false.

c. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented and/or clearly implied that CMC had "surprising" properties as a solubility enhancing agent, an adhesive agent, and/or a solubility enhancing and an adhesive agent. That representation and/or implication was false.

d. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented and/or clearly implied that its alleged invention was patentable as an "invention of selection." That representation and/or implication was false and/or misleading because the invention of selection argument was inapplicable.

e. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented and/or clearly implied that the other "vehicles" disclosed in Burke did not have solubility enhancing properties, when it believed otherwise.

f. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO, the best mode contemplated by the inventor(s) of carrying out the invention. Among other things, Allergan had filed a New Drug Application ("NDA") for a commercial product, which reflected the subject matter claimed by the '210 patent, shortly before filing the earliest application giving rise to the '210 patent. Whereas the NDA disclosed, inter alia, a "therapeutically effective aqueous composition" with brimonidine "in an amount effective to provide a therapeutic effect" and a polyanionic SEC "in an amount effective to increase the solubility of the brimonidine, that composition was not disclosed in the '210 patent.

g. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO, the existence of prior published information contradicting its representations with respect to adhesive properties of the "vehicles" disclosed in Burke, including: but not limited to:

i. Greaves et al., 1992, *STP Pharma Sci.*, 2: 13-33

ii. J.D. Smart, 1984, *J. Pharmacol.*, 36:295-299

iii. M.F. Saettone, 1984, *Int'l J Pharmaceutics*, 20: 187-202

h. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO, information contradicting its representations with respect to the solubilizing properties of the "vehicles" disclosed in Burke.

i. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO, other information contradicting its representations with respect to adhesive properties of the "vehicles" disclosed in Burke.

62. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that at the time of filing, and during the prosecution of '834 patent application, Allergan made misrepresentations and/or omissions of material facts to the Patent Examiner and the United States Patent Office: including, but not limited to:

a. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented and/or clearly implied that it was "surprising" that the concentration of active ingredient in a therapeutically effective composition could be reduced by adjusting the composition's pH closer to the pKa of the active ingredient. That representation and/or implication was false.

b. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented that it was "truly unexpected" that "a therapeutically effective dosage could be provided

by a composition containing about 0.15% or less of brimonidine" at a pH greater than about 7.0. That representation was false.

c. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO, the best mode contemplated by the inventor(s) (whether named on the '834 patent or not) of carrying out the invention. Among other things, Allergan had filed an NDA for a commercial product, which reflected the subject matter claimed by the '834 patent, shortly before filing the earliest application giving rise to the '834 patent. Whereas the NDA disclosed, *inter alia,* a therapeutically effective aqueous ophthalmic composition with 0.15% brimonidine, that composition was not disclosed in the '834 patent.

d. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO, the existence of prior published information demonstrating the efficacy of brimonidine at concentrations of "up to about 0.1596," including, but not limited to:

i. Derick et al., 1997, *Ophthalmol.*, 104:131-136

ii. Walters T, 1996, *Survey of Ophthalmol.*, 41:S19-S26

e. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO, the existence of prior published information demonstrating the effect of pH on drug bioavailability, including, but not limited to:

i. Olejnik, O., 1992, *Ophthalmic Drug Delivery Systems* (Ashim Mitra, ed.) pp. 177-198.

ii. Wilson et al., 1981, *J. Pharm. Pharmacol.*, 31:749-53.

iii. Small et al., 1997, *Int'l J. Pharmaceutics*, 149:195-201.

iv. Chien et al., 1990, *Current Eye Res.*, 9:1051-1059.

63. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that at the time of filing, and during the prosecution of the '337 patent application, Allergan made misrepresentations and/or omissions of material facts to the Patent Examiner and the United States Patent Office, including, but not limited to:

a. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented that "nothing in Burke discloses or suggests the use of a solubility enhancing component in combination with an alpha adrenergic agonist." Allergan clearly understood that Burke disclosed an alpha adrenergic agonist in combination with a "vehicle," and failed to disclose its belief that nearly all of the "vehicles" disclosed in Burke functioned as solubility enhancing components (albeit not labeled as such).

b. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan represented and/or clearly implied that its patent application was, to the Applicants' knowledge, the first reference to disclose the advantages of using a solubility enhancing component, "such as greater flexibility with the concentration and pH

at which such composition is formulated." That representation and/or implication was false.

c. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO, the best mode contemplated by the inventor(s) of carrying out the invention. Among other things, Allergan had filed an NDA for a commercial product, which reflected the subject matter claimed by the '337 patent, shortly before filing the earliest application giving rise to the '337 patent. Whereas the NDA disclosed, inter alia, a "therapeutically effective aqueous composition" with brimonidine "in an amount effective to provide a therapeutic effect" and an SEC "in an amount effective to increase the solubility of" the brimonidine, that composition was not disclosed in the '337 patent.

d. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan suppressed, and failed to disclose to the PTO prior published information contradicting its representation that, to the Applicants' knowledge, the '337 patent's specification was the first reference to disclose the advantages of using a solubility enhancing component, "such as greater flexibility with the concentration and pH at which such composition is formulated," including, but not limited to, the references identified in paragraphs 61 and 62.

64. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the representations and/or omissions set forth in paragraphs 61, 62 and 63 were false and/or misleading.

65. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the representations and/or omissions set forth in paragraphs 61, 62 and 63 were material to the prosecution of the '210, '834 and/or '337 patents.

66. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the representations and/or omissions set forth in paragraph 61 were material to the prosecution of the '210, '834 and '337 patents.

67. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the representations and/or omissions set forth in paragraph 62 were material to the prosecution of the '210, '834 and '337 patents.

68. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the representations and/or omissions set forth in paragraph 63 were material to the prosecution of the '337 patent.

69. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the representations and/or omissions set forth in paragraphs 61, 62 and 63 were known, or should have been known, by Allergan to be false and/or misleading prior to the issuance of the '210, '834 and/or '337 patents.

70. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan knew, or should have known, that the representations and/or omissions set forth in paragraphs 70, 71 and 72 were material to the prosecution of the '210, '834 and/or '337 patents.

71. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the representations and/or omissions set forth in

paragraphs 61, 62 and 63 were made with the intent to, and/or did, deceive the PTO, and were intended to, and/or did, induce the issuance of the '210, '834 and/or '337 patents.

72. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan (including, without limitation, its inventors, attorneys, and/or others involved in the filing and/or prosecution of the '210, '834 and/or '337 patents) owed a duty of candor and good faith to the United States Patent and Trademark Office.

73. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the first named inventor of the '210, '834 and '337 patents, Orest Olejnik, owed a duty of candor and good faith to the United States Patent and Trademark Office.

74. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that an attorney who prosecuted the '210, '834 and '337 patents for Allergan, Carlos A. Fisher, owed a duty of candor and good faith to the United States Patent and Trademark Office.

75. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that Allergan (including, without limitation, its inventors, attorneys, and/or others involved in the filing and/or prosecution of the '210, '834 and/or '337 patents) breached that duty of candor and good faith.

76. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the first named inventor of the '210, '834 and '337 patents, Orest Olejnik, breached his duty of candor and good faith to the United States Patent and Trademark Office.

77. After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that an attorney who prosecuted the '210, '834 and '337 patents for Allergan, Carlos A. Fisher, breached his duty of candor and good faith to the United States Patent and Trademark Office.

COUNT V—MISUSE

88. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 87 as though set forth fully herein.

89. The '078, '873, '210, '337 and '834 patents are invalid and/or were obtained improperly and by inequitable conduct. Knowing that the '078, '873, '210, '337 and '834 patents are invalid and/or unenforceable, Allergan commenced this infringement action against Apotex Inc. and Apotex Corp. Allergan's efforts to enforce the '078, '873, '210, '337 and '834 patents, by suing for infringement and by maintaining the patents' listings in the Approved Drug Products With Therapeutic Equivalence Evaluation (also known as the "Orange Book"), constitute patent misuse.

COUNT V—NON-INFRINGEMENT

90. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 89 as though set forth fully herein.

91. Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid, enforceable claim of the '078, '873, '210, '337 and '834 patents. ANDA applications 78-479 and 78-480 do not infringe, either directly or indirectly, any valid, enforceable claim of the '078, '873, '210, '337 and '834 patents. The proposed

products for which approval is sought under ANDA applications 78-479 and 78-480 do not directly or indirectly infringe any valid claim of the '078, '873, '210, '337 and '834 patents.

DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

a. Finding that the '078, '873, '210, '377 and '834 patents are invalid and unenforceable;

b. Finding that the '078, '873, '210, '377 and '834 patents are not infringed in any manner by either Apotex Inc. or Apotex Corp.;

c. Finding that this is an exceptional case under 35 U.S.C. § 285;

d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand a trial by jury on all issues appropriately tried to a jury.

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Dated: June 11, 2007
800700 / 31920

Attorneys for Defendants
Apotex Inc. and Apotex Corp.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on June 11, 2007, the attached document was hand delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF:

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I hereby certify that on June 11, 2007, I have Electronically Mailed the foregoing document(s) to the following non-registered participants:

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800744 / 31920

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 07-204-SLR
	)	
APOTEX INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S
ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants, Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the complaint of MedPointe Healthcare Inc. ("Plaintiff" or "MedPointe"), state and allege as follows:

PARTIES

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

ANSWER: Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 1 of the Complaint, and therefore deny same.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

ANSWER: Admitted.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Admitted.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Admitted.

5. Upon information and belief, Apotex Corp. is the United States agent for Apotex Inc. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

ANSWER: Apotex Inc. and Apotex Corp. admit that in ANDA 78-621 filed by Apotex Inc., Apotex Inc. designated Apotex Corp. as its agent in the United States for all matters related to ANDA 78-621; otherwise denied.

6. Upon information and belief, Apotex Corp. is the United States marketing and sales agent for Apotex Inc. wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Apotex Inc. manufactures and supplies the approved generic drug products to Apotex Corp., which then markets and sells those products throughout the United States, including in this judicial district, following any FDA approval.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. markets and sells generic drug products manufactured by Apotex Inc. throughout the United States, including in this judicial district, following FDA approval; otherwise denied.

7. Upon information and belief, and consistent with its practice with respect to other generic products, Apotex Inc. will sell the generic product accused of infringement in this Complaint through Apotex Corp. throughout the United States, including in this judicial district, following any FDA approval.

ANSWER: Denied, except to admit that Apotex Inc. intends to sell the generic product accused of infringement in this Complaint through Apotex Corp. throughout the United States following any FDA approval, unless there is Court intervention.

8. Upon information and belief, Apotex Corp. is the United States subsidiary and alter ego of Apotex Inc. Upon information and belief, for all purposes relevant to this action, Apotex Inc. and Apotex Corp. are effectively the same entity and are referred to collectively hereinafter as Apotex.

ANSWER: Denied.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

ANSWER: Apotex Inc. and Apotex Corp. admit that MedPointe purports to bring an action under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, for the alleged infringement of United States Patent No. 5,164,194; otherwise denied.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admitted.

11. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. is a Delaware corporation.

ANSWER: Admitted that this Court has personal jurisdiction over Apotex Corp. for this action.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; (3) its performance of acts, either directly or through an agent, that have caused tortious injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego; (4) its consent to personal jurisdiction in this Court in connection with another action for infringement of the '194 patent, Civil Action No. 06-164-SLR.

ANSWER: Denied, except to admit that this Court has personal jurisdiction over Apotex Inc. for this action.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

ANSWER: Admitted.

THE PATENT

14. On November 17, 1992, the '194 patent, titled "Azelastine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

ANSWER: Apotex Inc. and Apotex Corp. admit that the '194 patent, entitled "Azelastine Containing Medicaments," was issued by the United States Patent and Trademark Office on November 17, 1992, that Asta Pharma AG is listed as the assignee, and that a document purporting to be a copy of the '194 patent is attached to the Complaint. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of paragraph 14, and therefore deny same. Defendants deny all other allegations in paragraph 14.

ACTS GIVING RISE TO THIS ACTION

15. Upon information and belief, on or about December 13, 2006, Apotex submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted ANDA 78-621 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) on or about December 13, 2006.

16. ANDA 78-621 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic ophthalmic solution product containing 0.05% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal allergic rhinitis ("the Generic Product"). ANDA 78-621 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

ANSWER: Denied, except to admit that ANDA 78-621 seeks FDA approval to engage in the commercial manufacture, use, offer for sale and sale of a proposed drug

product as defined in ANDA 78-621 and that ANDA 78-621 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the '194 patent.

17. ANDA 78-621 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written notification of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation on March 14, 2007.

ANSWER: The first sentence of paragraph 17 of the Complaint is admitted. With regard to the second sentence in paragraph 17, Apotex Inc. and Apotex Corp. admit that Apotex Inc. sent written notification of ANDA 78-621 to MedPointe on or about March 12, 2007.

18. Upon information and belief, consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the United States for purposes of filing ANDA 78-621 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 78-621.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. markets and sells generic drug products manufactured by Apotex Inc. throughout the United States following FDA approval. Apotex Inc. and Apotex Corp. further admit that in ANDA 78-621 filed by Apotex Inc., Apotex Inc. designated Apotex Corp. as its agent in the United States for all matters related to ANDA 78-621; otherwise denied.

19. Apotex's submission of ANDA 78-621 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Denied.

20. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.

ANSWER: Denied.

21. Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. This is so because, upon information and belief, Apotex Inc. submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and will, *inter alia*, manufacture, offer to sell and sell the Generic Product upon receipt of any FDA approval of ANDA 78-621.

ANSWER: Denied, except to admit that Apotex Inc. submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

22. Apotex Inc.'s submission of ANDA 78-621 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex Inc. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271 (a), (b) and/or (c).

ANSWER: Denied.

23. Apotex Corp. is jointly and severally liable for the infringement of the '194 patent, regardless of which Apotex entity actually filed ANDA 78-621 and regardless of whether it is treated as the alter ego of Apotex Inc. for purposes of this action. This is so because, upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA and will, *inter alia*, offer to sell and sell the Generic Product within the United States and this judicial district upon receipt of any FDA approval of ANDA 78-621.

ANSWER: Denied.

24. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex Corp. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271 (a), (b) and/or (c).

ANSWER: Denied.

25. Apotex had actual and constructive notice of the '194 patent prior to filing ANDA 78-621.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. was aware of the '194 patent at the time it filed ANDA 78-621; otherwise denied.

26. MedPointe will be irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. MedPointe does not have an adequate remedy at law. Both the balance of the hardships as between MedPointe and Apotex and the public interest further support this Court enjoining Apotex's infringing activities.

ANSWER: Denied.

DEFENSES

FIRST DEFENSE: INVALIDITY

27. The '194 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

SECOND DEFENSE: ANTICIPATION

28. The '194 patent is invalid under 35 U.S.C. § 102 over prior art including, for example, United States Patent Nos. 3,813,384 and 4,704,387.

THIRD DEFENSE: OBVIOUSNESS

30. The '194 patent is invalid under 35 U.S.C. § 103 over prior art including, for example, United States Patent Nos. 3,813,384; 4,704,387; 3,878,217; 4,254,129; 4,313,931; 4,430,343; Pecoud, A., et al., *International Archives of Allergy and Applied Immunology* (1987), Vol. 82, pp. 541-543; Feinberg, S. M., *Transactions American Academy of Ophthalmology and Otolaryngology* (1950) Vol. 124, pp. 283-286; Kirkegaard, J., et al., *Allergy* (1982) Vol 37, pp. 203-208; Kirkegaard, J., et al., *British Journal of Diseases of the Chest* (1983) Vol. 77, pp. 113-12; Pipkorn, U., et al., *Allergy*

(1985) Vol. 40, pp. 491-496; Vanden Bussche, G., *Drugs of the Future* (1986) Vol. 11, pp. 841-843; Bende, M., et al., *Allergy* (1987), Vol. 42, pp. 512-515; Diamantis, W., et al., *Pharmacologist* (1981) Vol. 23, p. 149; Diamantis, W., et al., *Pharmacologist* (1982) Vol. 24, p. 200; and Kubo, N., et al., *Jpn. J. Pharmacol.* (1987) Vol. 43, pp. 277-82. The '194 patent is obvious in view of these references either individually, in combination with the knowledge of the person having ordinary skill in the art, or in combination with each other.

FOURTH DEFENSE: UNENFORCEABILITY

32. The '194 patent is unenforceable because it was procured through inequitable conduct. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for the '194 patent misled the PTO about the properties of the alleged invention claimed therein. More particularly, circumstances constituting the applicants' inequitable conduct include, but are not limited to, affirmative misrepresentations regarding the advantages and benefits of azelastine administered to prophylactically treat allergies.

33. On August 12, 1985, Jurgen Engel and Gerhard Scheffler filed an application in the PTO claiming compounds that were derivatives of azelastine and like azelastine were antiallergic and antiasthma prophylactically active. The applicants argued the compounds were better than azelastine because they could be applied as an aerosol with no, or considerably less, bitter taste. On February 16, 1987, a declaration was filed in support of patentability of the derivative compounds wherein the declarant asserted the derivatives of azelastine were superior to azelastine because "[azelastine] cannot be applied in the form of an aerosol" and that "use as an aerosol is especially

important for antiallergic and asthma prophylactic compounds." The declarant also argued the compounds of Examples 2 and 4 of the application "have almost 3 times as strong an antiallergic and asthma prophylactic action as [azelastine]." The declarant was an employee of Asta-Werke, but failed to disclose this fact to the PTO. The application later issued as U.S. Patent No. 4,704,387 ("the '387 prior art patent").

34. On November 13, 1987, less than nine months from the date the declaration was filed in support of the Engel and Scheffler application, Helmut Hettche filed an application in the Federal Republic of Germany claiming azelastine containing medicaments. The application claimed azelastine medicaments administered as aerosols to prophylactically treat allergy. The application further claimed that azelastine containing medicaments administered as aerosols resulted in no bitter taste side effect. On July 12, 1990, Helmut Hettche filed an application in the United States Patent Office claiming foreign priority to the application filed in the Federal Republic of Germany on November 13, 1987.

35. On February 12, 1990, a declaration was filed in support of the '194 patent application and to overcome an obviousness rejection based in part on the '387 prior art patent. The declarant argued azelastine was twice as effective as the compound of Example 1 of the '387 prior art patent. The applicants prosecuting the patent argued these results were surprising and unexpected and supported a finding that the '194 medicaments were not obvious in view of the '387 patent. The applicants failed to inform the examiner that the '387 patent claimed five different compounds and that Example 4 was structurally closer to azelastine and should have been compared to

azelastine. The examiner, nonetheless, rejected the declaration anyway because there was an incomplete recitation of the study protocol used to obtain the results.

36. In response to the examiner's criticism of the declaration, the applicants filed a second declaration purporting to further describe the experimental method of the first experiment. However, that declaration did not describe the experiment conducted in the first declaration. Instead, it described a hypothetical experiment that involved application of azelastine directly to the nasal mucosa of research animals, an *in vivo* test. This test would have been more probative of the patentability of the application. However, the test that was actually conducted and described in the first declaration was an *in vitro* test that involved studying the effects of the drug on cells suspended in a buffered solution. The same declarant drafted both the first and second declarations and knew the second declaration did not describe the experiments actually conducted and could not be used to support patentability. The declarant was also an employee of Asta-Werke, but failed to disclose this fact to the PTO. The application later issued as U.S. Patent No. 5,164,194, the patent in dispute.

37. Helmut Hettche and Jurgen Engel participated in a scheme to materially misrepresent to the PTO the advantages and disadvantages of azelastine and derivative azelastine compounds in an effort to obtain a patent monopoly on azelastine medicines and derivative medicines of azelastine. Jurgen Engel made knowingly false statements to the PTO in pursuing an application for azelastine derivatives. But for these statements, Jurgen Engel would not have been granted the '387 patent. Helmut Hettche later made knowingly false statements to the PTO in pursuing his application for azelastine

containing medicines. But for these statements, Helmute Hettche would not have been granted the '194 patent application leading to the '387 patent application.

38. Jurgen Engel was an employee at Asta-Werke while the applications leading to the '194 patent were filed and prosecuted. Helmut Hettche was also an employee of Asta-Werke and was a subordinate employee to Jurgen Engel at the time those applications were being filed. Helmut Hettche knew of the application leading to the '387 patent claiming derivative compounds to azelastine. Helmut Hettche participated in the development and testing of those compounds and was aware of the statements made in the application and prosecution. Jurgen Engel was also aware Hettche was developing the medicaments claimed in the '194 patent, including an aerosol of azelastine at the time he filed the application resulting in the '387 patent. In fact, both applications were prosecuted by the same U.S. law firm.

39. Helmut Hettche was aware that at least the compounds of Examples 2 and 4 of the '387 patent were almost 3 times more effective as antiallergy compounds than azelastine. Nonetheless, when prosecuting the application that resulted in the '194 patent, Hettche represented to the PTO that azelastine was twice as effective as the compound of Example 1 of the '387 patent, and that this result demonstrated azelastine was surprisingly and unexpectedly superior to the compounds disclosed in the '387 patent. Although Helmut Hettche knew the compounds of Examples 2 and 4 of the '387 patent were nearly three times as effective as azelastine, Hettche intentionally failed to disclose this fact to the PTO. The applicant knew that if he demonstrated the superior properties of the '387 compounds he would not be able to overcome a prima facie finding of obviousness by the examiner.

40. Helmut Hettche was also aware that Jurgen Engel had previously disclosed the superiority of the '387 patent compounds to the PTO. In an effort to further argue azelastine was superior to the compounds disclosed in the '387 patent and to throw the Examiner off track, the applicant misrepresented study protocols and results described in the first declaration filed in support of the application. These misrepresentations were designed to make the method of application of azelastine claimed in the '194 patent application appear superior to application of the compounds disclosed in the '387 patent administered in the same manner. In fact, Hettche never presented results of these types of comparison studies.

41. Helmut Hettche also misrepresented the state of the prior art in seeking to overcome the examiner's rejection of the Hettche application as anticipated by United States Patent No. 3,813,384 ("the '384 prior art patent"). In the paragraph bridging columns 6 and 7 of that patent, the '384 patent discloses administering azelastine "in the usual embodiments such as tablets, dragees, capsules, suppositories, drops, ointments, creams as well as injection solutions." The applicants of the '194 patent argued that this reference as interpreted by a person skilled in the art does not disclose that drops are administered to the patient. However, the applicants knew that Jurgen Engel had already argued to the PTO that the ability to administer antiallergic compounds as aerosols were important for the treatment of conditions described in the '194 patent application. It is well known in the art that aerosols are a form of administering drops. In fact, the '194 patent application admits drops are routinely administered to patients to treat allergies wherein at column 2, lines 12 through 17 the applicant states the preferred methods of administering azelastine are in the forms of "drops, ointments, [and] creams ..." These

were the exact modes of administering azelastine as disclosed in the '384 patent. Nonetheless, the applicants for the '194 patent continued to attempt to confuse and confound the examiner by arguing that one skilled in the art would not have understood the drops of azelastine disclosed in the '384 patent to be administered directly to the patient.

FIFTH DEFENSE: MISUSE

42. The '194 patent is invalid and was obtained improperly and by inequitable conduct. Knowing that the '194 patent is invalid MedPointe commenced this infringement action against Apotex. MedPointe's efforts to enforce the '194 patent, by suing for infringement and by maintaining the patent's listing in the Approved Drug Products With Therapeutic Equivalence Evaluation (also known as the "Orange Book"), constitute patent misuse.

SIXTH DEFENSE: NON-INFRINGEMENT

43. Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid claim of the '194 patent. ANDA 78-621 does not infringe any valid claim of the '194 patent. The proposed drug product for which approval is sought under ANDA 78-621 does not directly or indirectly infringe any valid claim of the '194 patent.

COUNTERCLAIMS

Counterclaimants Apotex Inc. and Apotex Corp. for their counterclaims against counter-defendant MedPointe Healthcare Inc. ("MedPointe") allege as follows:

PARTIES AND JURISDICTIONS

1. Apotex, Inc. is a Canadian corporation having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

4. MedPointe purports to be the sole owner of United States Patent No. 5,164,194 ("the '194 patent"), entitled "Azelastine Containing Medicaments."

5. Apotex Inc. has submitted an Abbreviated New Drug Application ("ANDA") 78-621 for a proposed drug product containing azelastine hydrochloride for ocular administration.

6. Pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii) and 21 C.F.R. § 314.95, Apotex Inc. certified to MedPointe that the '194 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the proposed drug for which ANDA 78-621 is submitted.

7. MedPointe has commenced this civil action against Apotex Inc. and Apotex Corp. alleging patent infringement.

8. This case arises under the Constitution, laws, or treaties of the United States, viz., 35 U.S.C. §§ 1-376, which is an Act of Congress relating to patents, and 21 U.S.C. § 355, which provides subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 271(e)(5).

9. Venue and personal jurisdiction are proper in this district because MedPointe, *inter alia*, is subject to personal jurisdiction in this judicial district and has submitted itself to the jurisdiction of this Court.

10. A real, actual, and justiciable controversy exists between Apotex Inc. and Apotex Corp. on the one hand and MedPointe on the other hand regarding the invalidity of the '194 patent and Apotex's non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 (2005).

COUNT I—DECLARATION OF INVALIDITY

11. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 10 as though set forth fully herein.

12. The '194 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT II—DECLARATION OF ANTICIPATION

13. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 12 as though set forth fully herein.

14. The '194 patent issued November 17, 1992 from patent application number 07/551,644 filed July 12, 1990, which purported to be a continuation of patent application number 07/268,772, filed November 9, 1988, and subsequently abandoned, which purported to claim priority from German patent application number 3738681, filed November 13, 1987.

15. United States Patent No. 3,813,384 ("the '384 prior art patent") is prior art with regard to the '194 patent under one or more of the provisions of 35 U.S.C. § 102.

16. United States Patent No. 4,704,387 ("the '387 prior art patent") is prior art with regard to the '194 patent under one or more of the provisions of 35 U.S.C. § 102.

17. The '194 patent is invalid under 35 U.S.C. § 102 over prior art including, for example, the '384 and '387 patents.

COUNT III—DECLARATION OF OBVIOUSNESS

18. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 17 as though set forth fully herein.

19. The scope and content of the prior art includes, but is not limited to, United States Patent Nos. 3,813,384; 4,704,387; 3,878,217; 4,254,129; 4,313,931; 4,430,343; Pecoud, A., et al., *International Archives of Allergy and Applied Immunology* (1987), Vol. 82, pp. 541-543; Feinberg, S. M., *Transactions American Academy of Ophthalmology and Otolaryngology* (1950), Vol. 124, pp. 284-286; Kirkegaard, J., et al., *Allergy* (1982), Vol. 37, pp. 203-208; Kirkegaard, J., et al., *British Journal of Diseases of the Chest* (1983), Vol. 77, pp. 113-122; Pipkorn, U., et al., *Allergy* (1985), Vol. 40, pp. 491-496; Vanden Bussche, G., *Drugs of the Future* (1986), Vol. 11, pp. 841-843; Bende, M., et al., *Allergy* (1987), Vol. 42, pp. 512-515; Diamantis, W., et al., *Pharmacologist* (1981), Vol. 23, p. 149; Diamantis, W., et al., *Pharmacologist* (1982), Vol. 24, p. 200; and Kubo, N., et al., *Jpn. J. Pharmacol.* (1987), Vol. 43, pp. 277-282. The '194 is obvious in view of these references either individually, in combination with the knowledge of the person having ordinary skill in the art, or in combination with each other.

20. The differences between the subject matter claimed in the '194 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

COUNT IV—DECLARATION OF UNENFORCEABILITY

21. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 20 as though set forth fully herein.

22. The '194 patent is unenforceable because it was procured through inequitable conduct. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for the '194 patent misled the PTO about the properties of the alleged invention claimed therein. More particularly, circumstances constituting the applicants' inequitable conduct include, but are not limited to, affirmative misrepresentations regarding the advantages and benefits of azelastine administered to prophylactically treat allergies.

23. On August 12, 1985, Jurgen Engel and Gerhard Scheffler filed an application in the PTO claiming compounds that were derivatives of azelastine and like azelastine were antiallergic and antiasthma prophylactically active. The applicants argued the compounds were better than azelastine because they could be applied as an aerosol with no, or considerably less, bitter taste. On February 16, 1987, a declaration was filed in support of patentability of the derivative compounds wherein the declarant asserted the derivatives of azelastine were superior to azelastine because "[azelastine] cannot be applied in the form of an aerosol" and that "use as an aerosol is especially

important for antiallergic and asthma prophylactic compounds." The declarant also argued the compounds of Examples 2 and 4 of the application "have almost 3 times as strong an antiallergic and asthma prophylactic action as [azelastine]." The declarant was an employee of Asta-Werke, but failed to disclose this fact to the PTO. The application later issued as the '387 prior art patent.

24. On November 13, 1987, less than nine months from the date the declaration was filed in support of the Engel and Scheffler application, Helmut Hettche filed an application in the Federal Republic of Germany claiming azelastine containing medicaments. The application claimed azelastine medicaments administered as aerosols to prophylactically treat allergy. The application further claimed that azelastine containing medicaments administered as aerosols resulted in no bitter taste side effect. On July 12, 1990, Helmut Hettche filed an application in the United States Patent Office claiming foreign priority to the application filed in the Federal Republic of Germany on November 13, 1987.

25. On February 12, 1990, a declaration was filed in support of the '194 patent application and to overcome an obviousness rejection based in part on the '387 prior art patent. The declarant argued azelastine was twice as effective as the compound of Example 1 of the '387 prior art patent. The applicants prosecuting the patent argued these results were surprising and unexpected and supported a finding that the '194 medicaments were not obvious in view of the '387 patent. The applicants failed to inform the examiner that the '387 patent claimed five different compounds and that Example 4 was structurally closer to azelastine and should have been compared to

azelastine. The examiner, nonetheless, rejected the declaration anyway because there was an incomplete recitation of the study protocol used to obtain the results.

26. In response to the examiner's criticism of the declaration, the applicants filed a second declaration purporting to further describe the experimental method of the first experiment. However, that declaration did not describe the experiment conducted in the first declaration. Instead, it described a hypothetical experiment that involved application of azelastine directly to the nasal mucosa of research animals, an *in vivo* test. This test would have been more probative of the patentability of the application. However, the test that was actually conducted and described in the first declaration was an *in vitro* test that involved studying the effects of the drug on cells suspended in a buffered solution. The same declarant drafted both the first and second declarations and knew the second declaration did not describe the experiments actually conducted and could not be used to support patentability. The declarant was also an employee of Asta-Werke, but failed to disclose this fact to the PTO. The application later issued as U.S. Patent No. 5,164,194, the patent in dispute.

27. Helmut Hettche and Jurgen Engel participated in a scheme to materially misrepresent to the PTO the advantages and disadvantages of azelastine and derivative azelastine compounds in an effort to obtain a patent monopoly on azelastine medicines and derivative medicines of azelastine. Jurgen Engel made knowingly false statements to the PTO in pursuing an application for azelastine derivatives. But for these statements, Jurgen Engel would not have been granted the '387 patent. Helmut Hettche later made knowingly false statements to the PTO in pursuing his application for azelastine

containing medicines. But for these statements, Helmute Hettche would not have been granted the '194 patent application leading to the '387 patent application.

28. Jurgen Engel was an employee at Asta-Werke while the applications leading to the '194 patent were filed and prosecuted. Helmut Hettche was also an employee of Asta-Werke and was a subordinate employee to Jurgen Engel at the time those applications were being filed. Helmut Hettche knew of the application leading to the '387 patent claiming derivative compounds to azelastine. Helmut Hettche participated in the development and testing of those compounds and was aware of the statements made in the application and prosecution. Jurgen Engel was also aware Hettche was developing the medicaments claimed in the '194 patent, including an aerosol of azelastine at the time he filed the application resulting in the '387 patent. In fact, both applications were prosecuted by the same U.S. law firm.

29. Helmut Hettche was aware that at least the compounds of Examples 2 and 4 of the '387 patent were almost 3 times more effective as antiallergy compounds than azelastine. Nonetheless, when prosecuting the application that resulted in the '194 patent, Hettche represented to the PTO that azelastine was twice as effective as the compound of Example 1 of the '387 patent, and that this result demonstrated azelastine was surprisingly and unexpectedly superior to the compounds disclosed in the '387 patent. Although Helmut Hettche knew the compounds of Examples 2 and 4 of the '387 patent were nearly three times as effective as azelastine, Hettche intentionally failed to disclose this fact to the PTO. The applicant knew that if he demonstrated the superior properties of the '387 compounds that he would not be able to overcome a prima facie finding of obviousness by the examiner.

30. Helmut Hettche was also aware that Jurgen Engel had previously disclosed the superiority of the '387 patent compounds to the PTO. In an effort to further argue azelastine was superior to the compounds disclosed in the '387 patent and to throw the Examiner off track, the applicant misrepresented study protocols and results described in the first declaration filed in support of the application. These misrepresentations were designed to make the method of application of azelastine claimed in the '194 patent application appear superior to application of the compounds disclosed in the '387 patent administered in the same manner. In fact, Hettche never presented results of these types of comparison studies.

31. Helmut Hettche also misrepresented the state of the prior art in seeking to overcome the examiner's rejection of the Hettche application as anticipated by the '384 prior art patent. In the paragraph bridging columns 6 and 7 of that patent, the '384 prior art patent discloses administering azelastine "in the usual embodiments such as tablets, dragees, capsules, suppositories, drops, ointments, creams as well as injection solutions." The applicants of the '194 patent argued that this reference as interpreted by a person skilled in the art does not disclose that drops are administered to the patient. However, the applicants knew that Jurgen Engel had already argued to the PTO that the ability to administer antiallergic compounds as aerosols were important for the treatment of conditions described in the '194 patent application. It is well known in the art that aerosols are a form of administering drops. In fact, the '194 patent application admits drops are routinely administered to patients to treat allergies wherein at column 2, lines 12 through 17 the applicant states the preferred methods of administering azelastine are in the forms of "drops, ointments, [and] creams ..." These were the exact modes of

administering azelastine as disclosed in the '384 patent. Nonetheless, the applicants for the '194 patent continued to attempt to confuse and confound the examiner by arguing that one skilled in the art would not have understood the drops of azelastine disclosed in the '384 patent to be administered directly to the patient.

32. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the foregoing misrepresentations and failure to disclose material prior art as set forth above were done with intent to mislead the PTO.

33. The facts and circumstances set forth in this Count IV constitute inequitable conduct on the part of the applicants, making the '194 patent unenforceable.

34. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for other and further circumstances constituting inequitable conduct by the applicants.

COUNT V—NON-INFRINGEMENT

35. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 34 as though set forth fully herein.

36. Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid claim of the '194 patent. ANDA 78-621 does not infringe, either directly or indirectly, any valid claim of the '194 patent. The proposed drug product for which approval is sought under ANDA 78-621 does not directly or indirectly infringe any valid claim of the '194 patent.

DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

a. Finding that the '194 patent is invalid and unenforceable;

b. Finding that the '194 patent is not infringed in any manner by either Apotex Inc. or Apotex Corp.;

c. Finding that this is an exceptional case under 35 U.S.C. § 285;

d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand trial by jury for all issues triable by jury. This demand is contingent upon MedPointe seeking monetary damages as set forth in paragraph D of its prayer for relief in its complaint.

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Dated: May 30, 2007
798352 / 30136-001

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on May 30, 2007, the attached document was hand delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF:

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I hereby certify that on May 30, 2007, I have Electronically Mailed the foregoing document(s) to the following non-registered participants:

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798407/30136-001

EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-164 (SLR)
	)	
APOTEX INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

ANSWER OF APOTEX INC. AND APOTEX CORP. TO PLAINTIFF'S AMENDED COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants, Apotex Inc. and Apotex Corp., Answer the Amended Complaint of Plaintiff, MedPointe Healthcare Inc., as follows:

PARTIES

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

ANSWER: Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of these averments in this paragraph.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

ANSWER: Admit that Apotex, Inc. is a corporation organized and existing under the laws of Canada and having a place of business at 380 Elgin Hills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Deny, except to admit that Apotex Inc. manufactures generic drug products that are approved by the United States Food and Drug Administration ("FDA") and that the approved drug products are sold in the United States.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Admit.

5. Upon information and belief, Apotex Corp. is the United States agent for Apotex Inc. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

ANSWER: Admit that Apotex Corp. is the United States agent for Apotex Inc. in matters relating to ANDA 77-954 arising before the United States Food and Drug Administration. Admit that Apotex Corp. is the United States agent for Apotex Inc. for service of process. Apotex denies all other allegations of paragraph 5.

6. Upon information and belief, Apotex Corp. is the United States marketing and sales agent for Apotex Inc. wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Apotex Inc. manufactures and supplies the approved generic drug products to Apotex Corp., which then markets and sells those products throughout the United States, including in this judicial district, following any FDA approval.

ANSWER: Deny, except to admit that following FDA approval of the proposed drug product, Apotex Corp. intends to sell Azelastine Hydrochloride Nasal Spray (the "proposed drug product") in the US.

7. Upon information and belief, and consistent with its practice with respect to other generic products, Apotex Inc. will sell the generic product accused of infringement in this Complaint through Apotex Corp. throughout the United States, including in this judicial district, following any FDA approval.

ANSWER: Deny, except to admit that following FDA approval of the proposed drug product, Apotex Inc. intends to supply Apotex Corp. with the proposed drug product for sale in the US.

8. Upon information and belief, Apotex Corp. is the United States subsidiary and alter ego of Apotex Inc. Upon information and belief, for purposes of this action, Apotex Inc. and Apotex Corp. are effectively the same entity and are referred to collectively hereinafter as Apotex.

ANSWER: Deny, except to admit that Apotex Inc. and Apotex Corp. are related companies and that Plaintiff may refer to them collectively as Apotex even though they are separate entities.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §100 *et seq*.

ANSWER: This paragraph contains MedPointe's characterization of its action and to which no answer is required, but insofar as an answer is required, deny.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admit.

11. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. is a Delaware corporation.

ANSWER: Admit.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; and (3) its performance of acts, either directly or through an agent, that have caused tortuous injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego.

ANSWER: Deny, except to admit that this Court has personal jurisdiction over Apotex, Inc. for this matter.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

ANSWER: Apotex admits that venue in this district is proper for this action

THE PATENT

14. On November 17, 1992, the '194 patent, titled "Azelastine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

ANSWER: Deny that the '194 patent was duly and legally issued on November 17, 1992. Admit that a document purporting to be U.S. Patent Number 5,164,194 was attached to the Complaint, and that Asta Pharma AG is listed thereon as assignee. With regard to the remaining allegations, Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of these averments, which has the effect of denial reasonably based on lack of information and belief.

ACTS GIVING RISE TO THIS ACTION

15. Upon information and belief, on or about November 14, 2005, Apotex submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

ANSWER: Deny, expect to admit that Apotex Inc. submitted ANDA 077954 to the FDA under §505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 335) on or about November 14, 2005.

16. ANDA 77-954 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal rhinitis ("the Generic Product"). ANDA 77-954 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

ANSWER: Admit that ANDA 77-954 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution having the name Azelastine Hydrochloride Nasal Spray (the "proposed product") for use in treating, *inter alia*, seasonal rhinitis, and that ANDA 77-954 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the '194 patent. The remaining allegations are denied.

17. ANDA 77-954 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written Notification of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation on January 27, 2005.

ANSWER: Admit that ANDA 77-954 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the proposed drug product. Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining averments, which has the effect of denial reasonably based on lack of information and belief.

18. In the written notification of ANDA 77-954, Apotex Inc. designated Apotex Corp. as its "agent in the United States authorized to accept service of process for Apotex."

ANSWER: Admit that in the written notification of ANDA 77-954, Apotex Inc. designated Apotex Corp. as its "agent in the United States authorized to accept service of process for Apotex."

19. Upon information and belief, and consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the

United States for purposes of filing ANDA 77-954 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 77-954.

ANSWER: Deny, except to admit that Apotex Inc. has designated Apotex Corp. as its agent in the United States in ANDA 77-954 to the extent required by FDA regulations and for service of legal process.

20. Apotex's submission of ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Admit that Apotex Inc. submitted ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation. All other averments of this paragraph are denied.

21. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.

ANSWER: Deny.

22. Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. This is so because, upon information and belief, Apotex Inc. submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and will, *inter alia*, manufacture, offer to sell and sell the Generic Product upon receipt of any FDA approval of ANDA 77-954.

ANSWER: Deny that Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. Admit that Apotex Inc. submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and intends to, *inter alia*, manufacture the proposed drug product upon receipt of FDA approval of ANDA 77-954.

23. Apotex Inc.'s submission of ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35

U.S.C. §271(e)(2)(A). Moreover, if Apotex Inc. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Admit that Apotex Inc. submitted ANDA 77-954 to the FDA, including the §505(j)(2)(A)(vii)(IV) allegation. All other averments of this paragraph are denied.

24. Apotex Corp. is jointly and severally liable for the infringement of the '194 patent, regardless of which Apotex entity actually filed ANDA 77-954 and regardless of whether it is treated as the alter ego of Apotex Inc. for purposes of this action. This is so because, upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA and will, *inter alia*, offer to sell and sell the Generic Product within the United States and this judicial district upon receipt of any FDA approval of ANDA 77-954.

ANSWER: Deny, except to admit that if ANDA 77-954 is approved, it is expected that Apotex Corp. would offer to sell and sell the proposed drug product in the United States.

25. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '194 patent under 35 U.S.C. § 271 (e)(2)(A). Moreover, if Apotex Corp. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Deny.

26. Apotex had actual and constructive notice of the '194 patent prior to filing ANDA 77-954.

ANSWER: Deny, except to admit that Apotex Inc. and Apotex Corp. had access to the FDA Orange Book which listed the '194 patent.

27. MedPointe will be irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. MedPointe does not have an adequate remedy at law.

ANSWER: Deny.

AFFIRMATIVE DEFENSES

FIRST DEFENSE: INVALIDITY

28. The '194 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

SECOND DEFENSE: ANTICIPATION

29. The '194 patent is invalid under 35 U.S.C. § 102 over prior art including, but not limited to, United States Patents No. 3,813,384 and 4,704,387.

THIRD DEFENSE: OBVIOUSNESS

30. The '194 patent is invalid under 35 U.S.C. § 103 over prior art including, but not limited to, United States Patents No. 3,813,384, 4,704,387, 3,878,217, 4,254,129, 4,313,931, 4,430,343, Pecoud, A., et al., *International Archives of Allergy and Applied Immunology* (1987), Vol. 82, pp 541-543, Feinberg, S. M., *Transactions American Academy of Ophthalmology and Otolaryngology* (1950) Vol. 124, pp. 283-286, Pipkorn, U., et al., *Allergy* (1985) Vol. 40, pp. 491-496, Vanden Bussche, G., *Drugs of the Future* (1986) Vol. 11, pp. 841-843, Bende, M., et al., *Allergy* (1987), Vol. 42, pp. 512-515, Diamantis, W., et al., *Pharmacologist* (1981) Vol. 23, p. 149, Diamantis, W., et al., *Pharmacologist* (1982) Vol. 24, p. 200 (abstract no. 82 574 presented at ASPET meeting Louisville Kentucky, Aug 15-19 1982), and Kubo, N. et al., *Jpn. J. Pharmacol.* (1987) Vol. 43, pp. 277-82. The '194 patent is obvious in view of these references either individually, in combination with the knowledge of the person having ordinary skill in the art, or in combination with each other.

FOURTH DEFENSE: UNENFORCEABILITY

31. The '194 patent is unenforceable as procured through inequitable conduct. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for that patent misled the PTO about the properties of the alleged invention claimed therein. More particularly, circumstances constituting the applicants' inequitable conduct include, but are not limited to affirmative misrepresentation regarding the benefits of azelastine administered as a nasal spray.

32. The '194 patent asserts that the surprising feature of the invention is that the azelastine formulations of the '194 patent cause neither somnolence nor the bitter taste side effects of previous azelastine formulations. However, bitter taste is a well known side-effect of azelastine intranasal spray, as disclosed in, for example, *Curr. Med. Res. Opin.* (1997), Volume 14, No. 1, pp 21. MedPointe admits in its product insert for Astelin® brand azelastine nasal spray (attached as Exhibit A) indicates that major side effects include bitter taste (19.7% of individuals), somnolence (11.5% of individuals) and fatigue (2.3% of individuals).

33. Also, during prosecution, the applicants argued, as an indicium of non-obviousness, that azelastine more effectively inhibited liberation of histamine compared with the prior art, the compound of Example 1 of United States Patent No. 4,704,387 even though Example 4 was closer to azelastine. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary support that such acts were done with the intent to mislead the PTO and to fraudulently extend patent protection of azelastine.

FIFTH DEFENSE: MISUSE

34. The '194 patent is invalid and obtained fraudulently and by inequitable conduct. MedPointe submitted the '194 patent to the FDA to be listed among Approved Drug Products With Therapeutic Equivalence Evaluation (also known as the "Orange Book") as covering azelastine hydrochloride. MedPointe also has commenced this infringement action against Apotex. MedPointe's efforts to enforce the '194 patent, by infringement suits and by listing that patent in the Orange Book, constitute patent misuse.

COUNTERCLAIMS

35. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege their specific responses and averments in paragraphs 1–26 above as if fully set forth herein.

PARTIES AND JURISDICTIONS

36. MedPointe has alleged that MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

37. Apotex, Inc. is Canadian corporation having a place of business at 150 Signet Drive, Weston, Ontario, Canada M9L 1 T9.

38. Apotex Corp. is a Delaware corporation having a place of business at place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

39. MedPointe manufactures and sells a pharmaceutical product under the trade name Astelin® that is a solution of azelastine hydrochloride for intranasal administration.

40. MedPointe was formed in 2001 when the healthcare division of Carter-Wallace was sold. One of the products included in the portfolio that became MedPointe was azelastine nasal spray.

41. MedPointe obtained approval from the Food and Drug Administration ("FDA") to market its Astelin® product pursuant to a New Drug Application ("NDA") 20-114 submitted by Carter-Wallace.

42. MedPointe has represented to the FDA that the '194 patent claims the use of the drug azelastine as a nasal spray.

43. Relying in part on NDA 20-114, Apotex Inc. has submitted an Abbreviated New Drug Application ("ANDA") No. 77-954 for a proposed drug product containing azelastine hydrochloride for intra-nasal administration.

44. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.95, Apotex Inc. and Apotex Corp. have certified to MedPointe that the '194 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the new drug for which ANDA 77-954 is submitted.

45. MedPointe has commenced this civil action against Apotex Inc. and Apotex Corp. alleging patent infringement.

46. This case arises under the Constitution, laws, or treaties of the United States, viz., 35 U.S.C. §§ 1–376, which is an Act of Congress relating to patents, and 21 U.S.C. 355, which provide subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

47. A real, actual, and justiciable controversy exists between Apotex Inc. and Apotex Corp. on the one hand and MedPointe on the other hand regarding the invalidity of the '194 patent and Apotex' non-infringement thereof, constituting a case of actual

controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202 (2005).

COUNT I — DECLARATION OF INVALIDITY

48. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege their specific responses and averments in paragraphs 1–47 above as though set forth fully herein.

49. The '194 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT II — DECLARATION OF ANTICIPATION

50. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege its specific responses and averments in paragraphs 1–49 above as though set forth fully herein.

51. The '194 patent issued Nov. 17, 1992 from Patent Application number 07/551,644 filed July 12, 1990, which purported to be a continuation of Patent Application number 07/268,772, filed November 9, 1988 and subsequently abandoned, and purports to claim priority from the German Patent Application number 373681 filed Nov. 13, 1987.

52. United States Patent No. 3,813,384 is prior art with regard to the '194 patent under one or more of the provisions of 35 U.S.C. § 102.

53. United States Patent No. 4,704,387 are prior art with regard to the '194 patent under one or more of the provisions of 35 U.S.C. § 102.

54. The '194 patent is invalid under 35 U.S.C. § 102 over prior art including, but not limited to, the prior art listed in ¶¶ 54-55 above.

COUNT III — DECLARATION OF OBVIOUSNESS

55. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege their specific responses and averments in paragraphs 1–54 above as though set forth fully herein.

56. The scope and content of the prior art includes, but is not limited to, United States Patents No. 3,813,384, 4,704,387, 3,878,217, 4,254,129, 4,313,931, 4,430,343, Pecoud, A., et al., *International Archives of Allergy and Applied Immunology* (1987), Vol. 82, pp 541-543, Feinberg, S. M., *Transactions American Academy of Ophthalmology and Otolaryngology* (1950) Vol. 124, pp. 283-286, Pipkorn, U., et al., *Allergy* (1985) Vol. 40, pp. 491-496, Vanden Bussche, G., *Drugs of the Future* (1986) Vol. 11, pp. 841-843, Bende, M., et al., *Allergy* (1987), Vol. 42, pp. 512-515, Diamantis W, et al., *Pharmacologist* (1981) Vol. 23, p. 149, Diamantis W, et al., *Pharmacologist* (1982) Vol. 24, pp. 200, and Kubo N et al., *Jpn. J. Pharmacol.* (1987) Vol. 43, pp. 277-82. The '194 patent is obvious in view of these references either individually, in combination with the knowledge of the person having ordinary skill in the art, or in combination with each other.

57. The differences between the subject matter claimed in the '194 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

COUNT IV — DECLARATION OF UNENFORCEABILITY

58. Apotex Inc. and Apotex Corp. adopt by reference, repeat, and reallege their specific responses and averments in paragraphs 1–57 above as though set forth fully herein.

59. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for the '194 patent misled the PTO about the properties of the alleged invention claimed therein. More particularly, circumstances constituting the applicants' inequitable conduct include, but are not limited to affirmative misrepresentation regarding the benefits of azelastine administered as a nasal spray.

60. The '194 patent asserts that the surprising feature of the invention is that the azelastine formulations of the '194 patent cause neither somnolence nor the bitter taste side effects of previous azelastine formulations. However, bitter taste is a well known and common effect of azelastine nasal spray administration, as disclosed in, for example, *Curr. Med. Res. Opin.* (1997), Volume 14, No. 1, pp 21. MedPointe admits in its product insert for Astelin® brand azelastine nasal spray (attached as Exhibit A) indicates that major side effects include bitter taste (19.7% of individuals), somnolence (11.5% of individuals) and fatigue (2.3% of individuals).

61. Also, during prosecution, the applicants argued, as an indicium of non-obviousness, that azelastine more effectively inhibited liberation of histamine compared with the prior art, the compound of Example 1 of United States Patent No. 4,704,387 even though Example 4 was closer to azelastine. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary

support that such acts were done with the intent to mislead the PTO and to fraudulently extend patent protection of azelastine.

62. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary support that the foregoing misrepresentations and failure to disclose material prior art as set forth above were done with intent to mislead the PTO.

63. The facts and circumstances set forth in this Count IV constitute inequitable conduct on the part of Applicants, making the '194 patent unenforceable.

64. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for other and further circumstances constituting inequitable conduct by the applicants.

DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

a. Finding that the '194 patent is invalid and unenforceable;

b. Finding that the '194 patent is not infringed;

c. Finding that this is an exceptional case under 35 U.S.C. § 285;

d. Awarding to Apotex Inc. and Apotex Corp. its costs, expenses, and reasonable attorneys' fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

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Dated: April 14, 2006
728036 / 30136

By: */s/ Richard L. Horwitz*
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on April 14, 2006, the attached document was hand delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF:

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I hereby certify that on April 14, 2006, I have Electronically Mailed the foregoing document(s) to the following non-registered participants:

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EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	C.A. No. 08-65-SLR
v.	)	
APOTEX INC. and APOTEX CORP.	)	
Defendants.	)	

DEFENDANTS APOTEX, INC.'S AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendants Apotex, Inc. and Apotex Corp. (collectively "Apotex") for their Answer, Affirmative Defenses and Counterclaims to Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc.'s ("Boehringer") Complaint state as follows:

PARTIES

1. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. (hereinafter "Plaintiff" or "Boehringer") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

ANSWER:

Admitted, upon information and belief

2. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of the Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

ANSWER:

Admitted.

3. On information and belief, defendant Apotex Inc. manufactures numerous generic drugs for sale, distribution, and use throughout the United States, including this judicial district.

ANSWER:

Apotex admits that Apotex, Inc. manufactures generic drug products for sale, distribution and use throughout the United States, including this judicial district.

4. On information and belief, Apotex Corp. is a corporation incorporated under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER:

Admitted.

5. On information and belief, Apotex Corp. sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

ANSWER:

Apotex admits that Apotex Corp. sells generic drug products manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

6. Apotex Inc. and Apotex Corp. are hereinafter collectively referred to as "Apotex."

ANSWER:

Paragraph 6 fails to state an allegation, and thus, Apotex is not required to provide an answer or response to paragraph 6.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

Admitted.

8. Apotex sells various products and does business throughout the United States, including within this judicial district.

ANSWER:

Apotex admits that Apotex Corp. sells products and does business throughout the United States, including within this judicial district.

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 28 U.S.C. § 1400(b).

ANSWER:

Admitted.

BACKGROUND

10. United States Patent No. 5,098,715 ("the '715 patent") was duly and legally issued on March 24, 1992, to Burroughs Wellcome Co., the assignee of named inventors Terrance T. McCabe, Robert A. Stagner, and Joel E. Sutton, Jr.

ANSWER:

Apotex admits that a copy of what purports to be United States Patent No. 5,098,715 ("the '715 patent") is attached to Boehringer's Complaint as Exhibit A. On its face, Exhibit A lists: an issue date of March 24, 1992; inventors Terrance T. McCabe, Robert A. Stagner and Joel E. Sutton, Jr.; and assignee Burroughs Wellcome Co. Apotex denies all remaining allegations contained in paragraph 10.

11. The '715 patent was subsequently assigned to Boehringer. Boehringer is the current assignee of all right, title, and interest in the '715 patent, including the right to sue for infringement of that patent. The '715 patent is presently scheduled to expire on December 20, 2010.

ANSWER:

Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments contained in paragraph 11, and therefore denies the same and demands strict proof thereof.

12. The '715 patent describes and claims, among other things, a flavored film-coated pharmaceutical tablet and a method of preparing flavor-coated pharmaceutical tablets. A true and correct copy of the '715 patent is attached hereto as Exhibit A.

ANSWER:

Apotex admits that what purports to be a copy of the '715 patent is attached to Boehringer's Complaint as Exhibit A. Apotex denies all remaining allegations contained in paragraph 12.

13. On August 31, 2004 the United States Food and Drug Administration ("FDA") approved new drug application ("NDA") No. 02-1698, Product Number 001 for ZANTAC® 150, a pharmaceutical composition containing Ranitidine Hydrochloride, under § 505(a) of the

Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 335(a). On March 13, 2007, the United States FDA approved NDA No. 02-1698, Product Number 002 for ZANTAC® 150, a pharmaceutical composition containing Ranitidine Hydrochloride, under § 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 335(a). Boehringer is the holder of approved NDA No. 02-1698 for Ranitidine Hydrochloride tablets OTC, which are sold under the trademarks and

trade names ZANTAC® 150 and ZANTAC® 150 Cool (hereinafter the "ZANTAC® 150 OTC products").

ANSWER:

Apotex admits on information and belief that the United States Food and Drug Administration's ("FDA") website lists an approval letter for New Drug Application ("NDA") No. 02-1698 dated August 31, 2004. Apotex further admits on information and belief that the FDA's website lists NDA No. 02-1698 as an over-the-counter ("OTC") drug product and the holder of NDA No. 02-1698 as "Boehringer Ingelheim." Apotex is without knowledge or information sufficient to form a belief as to the truth of the remaining averments contained in paragraph 13, and therefore denies the same and demands strict proof thereof.

14. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. The '715 patent is listed in the Orange Book for ZANTAC® 150 OTC tablets.

ANSWER:

Apotex admits on information and belief that the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the '715 patent under reference listed drug NDA No. 02-1698, product no. 002. Apotex is without knowledge or

information sufficient to form a belief as to the truth of the remaining averments contained in paragraph 14, and therefore denies the same and demands strict proof thereof.

15. On information and belief, Apotex submitted to the FDA abbreviated new drug application ("ANDA") No. 79-127 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of Ranitidine Hydrochloride tablets in the 150 mg strength as a generic version of the ZANTAC® 150 OTC products.

ANSWER:

Apotex admits that Apotex, Inc. submitted Abbreviated New Drug Application ("ANDA") No. 79-127 to FDA seeking approval to engage in the commercial manufacture, use and sale of its proposed 150 mg ranitidine hydrochloride tablets. Apotex denies all remaining allegations contained in paragraph 15.

16. On information and belief, Apotex Corp. is the United States agent for Apotex Inc. in matters relating to ANDA 79-127 arising before the United States Food and Drug Administration.

ANSWER:

Apotex admits that Apotex Corp. is listed as the United States Agent in Apotex's ANDA No. 79-127. Apotex denies all remaining allegations in paragraph 16.

17. In addition, Apotex Corp. is the United States agent for Apotex Inc. for service of process with respect to ANDA 79-127.

ANSWER:

Admitted with respect to ANDA No. 79-127.

18. On information and belief, upon receipt of final approval from the FDA, Apotex Corp. intends to market and sell Ranitidine Hydrochloride tablets, 150 mg OTC in the United States, including within this judicial district.

ANSWER:

Apotex denies all allegations contained in paragraph 18.

19. By letter dated December 18, 2007 (the "Apotex Letter"), Apotex advised Boehringer that it had submitted ANDA No. 79-127 seeking approval to engage in the commercial manufacture, use and/or sale of generic versions of ZANTAC® 150 OTC products prior to the expiration of the '715 patent. The Apotex Letter also advised Boehringer that Apotex's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Apotex's opinion, the products described in Apotex ANDA will not infringe any of the claims of the '715 patent. The Apotex Letter also indicates that Apotex may have an unstated further basis allegedly supporting its Paragraph IV certification.

ANSWER:

Apotex admits that in a letter dated December 19, 2007 ("notice letter") Apotex, Inc. advised Boehringer that it had submitted ANDA No. 79-127 seeking approval to engage in the commercial manufacture, use and/or sale of its proposed 150 mg ranitidine hydrochloride tablets prior to the '715 patent. Apotex further admits that Apotex, Inc.'s notice letter advised Boehringer that ANDA No. 79-127 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that Apotex, Inc.'s proposed 150 mg ranitidine hydrochloride tablets will not infringe any validly construed claim of the '715 patent and that Apotex may have further bases for its Paragraph IV certification. Apotex denies all remaining allegations contained in paragraph 19.

20. The Apotex Letter included an offer of confidential access to certain information from the Apotex ANDA, allegedly to afford Boehringer an opportunity to evaluate the information in connection with a determination whether to initiate an infringement action pursuant to 35 U.S.C. § 271(e)(2). Boehringer responded by attempting to accept Apotex's offer of confidential access by letter dated January 7, 2008 and received by Apotex on January 8, 2008. Apotex has not provided Boehringer with access to the requested documents, materials, and information.

ANSWER:

Apotex admits that Apotex, Inc.'s notice letter included an offer of confidential access pursuant to 21 U.S.C. 355(j)(5)(C)(i)(III). Apotex denies all remaining allegations contained in paragraph 20.

CLAIM FOR RELIEF

21. Plaintiff incorporates each of the preceding paragraphs 1 to 20 as if fully set forth herein.

ANSWER:

Apotex repeats and reasserts its responses set forth in paragraphs 1 - 20 as if set forth fully herein.

22. On information and belief, Apotex has committed an act of infringement of the '715 patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 79-127 containing a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of generic Ranitidine Hydrochloride OTC products before the expiration of the '715 patent.

ANSWER:

Apotex denies all allegations contained in paragraph 22.

23. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '715 patent.

ANSWER:

Apotex denies all allegations contained in paragraph 23.

24. Boehringer is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 79-127 be deemed not earlier than the December 20, 2010 expiration date of the '715 patent (including any subsequent extension thereof), and an injunction precluding Apotex from infringing the '715 patent.

ANSWER:

Apotex denies all allegations contained in paragraph 24.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Boehringer respectfully requests the following relief.

A. A judgment that Apotex has infringed the '715 patent by filing ANDA No. 79-127;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of Apotex's ANDA No. 79-127 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C § 355(j)) be a date which is not earlier than the expiration date of the '715 patent (including any extension thereof);

C. A permanent injunction, pursuant to 35 U.S.C § 271(e)(4)(B), restraining and

enjoining Apotex and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from infringement of the '715 patent for its full term (including any extension thereof);

D. A declaration that this is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

ANSWER:

Apotex specifically denies that Plaintiff is entitled to the general or specific relief requested against Apotex, or to any relief whatsoever, and prays for judgment in favor of Apotex dismissing this action with prejudice, and awarding Apotex its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Apotex, Inc. and Apotex Corp. aver and assert the following Affirmative Defenses to Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc.'s ("Boehringer") Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 5,098,715)

The manufacture, use, sale, offer to sell or importation into the United States of Apotex, Inc.'s or Apotex Corp.'s proposed 150 mg ranitidine hydrochloride tablets that are the subject of ANDA No. 79-127 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 5,098,715 (the '715 patent") either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 5,098,715)

Upon information and belief, the claims of the '715 patent are invalid and/or unenforceable for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112, and/or 37 CFR § 1.56.

COUNTERCLAIMS

1. Counterclaimant Apotex, Inc. is a corporation organized under the laws of Canada, and its principal place of business is located at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

2. Counterclaimant Apotex Corp. is a corporation incorporated under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Upon information and belief, Counterclaim Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (hereinafter "Plaintiff" or "Boehringer") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

4. As a consequence of Plaintiffs/Counterclaim Defendants' complaint against Apotex, Inc. and Apotex Corp. there is now an existing, continuing actual controversy between Boehringer and Apotex, Inc. and Apotex Corp., regarding the alleged infringement, validity and enforceability of U.S. Patent No. 5,098,715 ("the '715 patent").

5. This Court has jurisdiction over the subject matter of these counterclaims pursuant to §§ 1331 and 1338 (a) of Title 28 of the U.S. Code because they involve substantial claims arising out of the United States Patent Act, 35 U.S.C. § 1, *et. seq*.

6. This Court may declare the rights and legal relation for the parties pursuant to §§ 2201 and 2202 of Title 28 of the U.S. Code and § 271 (e)(5) of Title 35 of the U.S. Code because Apotex, Inc.'s and Apotex Corp.'s counterclaims present an actual controversy within the

Court's jurisdiction that the patent asserted by Plaintiff/Counterclaim Defendant against Defendants/Counterclaim Plaintiffs, Apotex, Inc. and Apotex Corp. is not infringed and/or is invalid.

7. Venue for these counterclaims is proper within this District in which Plaintiff/Counterclaim Defendant's Complaint is pending.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '715 PATENT

8. The manufacture, use, sale, offer to sell or importation into the United States of Apotex, Inc.'s or Apotex Corp.'s proposed 150 mg ranitidine hydrochloride tablets that are the subject of ANDA No. 79-127 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '715 patent either literally or under the doctrine of equivalents.

COUNT II
DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '715 PATENT

9. Upon information and belief, the claims of the '715 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Apotex, Inc. and Apotex Corp. respectfully request the Court to enter judgment against counterclaim defendants Boehringer as follows:

A. Declaring that Apotex, Inc.'s proposed 150 mg ranitidine hydrochlorides tablets that are the subject of ANDA No. 79-127 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '715 patent either literally or under the doctrine of equivalents.

B. Declaring that U.S. Patent No. 5,098,715 is invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, 102, 103, and/or 112.

C. Awarding Apotex, Inc. and Apotex Corp. their reasonable costs and attorneys fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and

D. Awarding all such other and further relief as this Court may deem just and proper.

Dated: February 21, 2008

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned on oath states that foregoing **APOTEX, INC.'S AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT** was served on the following counsel by electronic filing with the Court's ECF system and by placing a true and correct copy in the U.S. Mail on this 21st day of February, 2008.

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EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

DEFENDANT APOTEX, INC.'S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant, Apotex, Inc. ("Defendant" or "Apotex"), for its Answer, Affirmative Defenses, and Counterclaim, to the complaint of Merck & Co., Inc. ("Plaintiff" or "Merck"), states and alleges as follows:

THE PARTIES

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck drive, Whitehouse Station, New Jersey 08889.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

2. On information and belief, Defendant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. It has authorized Apotex Corp., incorporated under the laws of Delaware and with principal place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida 33326, to act as agent for service of process with respect to commencement of this patent infringement action.

ANSWER: Admitted.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

ANSWER: Apotex admits that Merck purports to bring an action under the patent laws of the United States of America and admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); otherwise denied.

4. Venue is proper in this court under Title 28, United States Code §§ 1391(c) and 1400(b), because the defendant has submitted to personal jurisdiction in this judicial district for this action.

ANSWER: Admitted.

BACKGROUND

5. On October 25, 1994, United States Letters Patent No. 5,358,941 (the "'941 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS WITH LACTOSE, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '941 patent is currently set to expire on December 2, 2012. The '941 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '941 patent is attached to this Complaint as Exhibit 1.

ANSWER: Apotex admits that United States Patent No. 5,358,941, entitled "Dry Mix Formulation For Bisphosphonic Acids With Lactose" was issued by the United States Patent and Trademark Office on October 25, 1994 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '941 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

6. On October 28, 1997, United States Letters Patent No. 5,681,590 (the "'590 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '590 patent is currently set to expire on December 2, 2012. The '590 patent discloses and claims novel pharmaceutical compositions and novel processes for manufacturing compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '590 patent is attached to this Complaint as Exhibit 2.

ANSWER: Apotex admits that United States Patent No. 5,681,590, entitled "Dry Mix Formulation For Bisphosphonic Acids" was issued by the United States Patent and Trademark Office on October 28, 1997 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '590 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

7. On December 15, 1998, United States Letters Patent No. 5,849,726 (the "'726 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '726 patent is currently set to expire on June 6, 2015. The '726 patent discloses and claims novel pharmaceutical compositions of anhydrous 4-amino-1-hydroxy-butylidene-1, 1-bisphosponic acid monosodium salt, as well as novel methods for treating and preventing bone loss with these compositions. A copy of the '726 patent is attached to this Complaint as Exhibit 3.

ANSWER: Apotex admits that United States Patent No. 5,849,726, entitled "Anhydrous Alendronate Monosidum Salt Formulations" was issued by the United States Patent and Trademark Office on Decmeber 15, 1998 to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies, and that a copy of the '726 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

8. On December 28, 1999, United States Letters Patent No. 6,008,207 (the "'207 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '207 patent is currently set to expire on June 6, 2015. The '207 patent discloses and claims novel methods for administering anhydrous alendronate monosodium salt formulations. A copy of the '207 patent is attached to this Complaint as Exhibit 4.

ANSWER: Apotex admits that United States Patent No. 6,008,207, entitled "Anhydrous Alendronate Monosidum Salt Formulations" was issued by the United States Patent and

Trademark Office on December 28, 1999 to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies, and that a copy of the '207 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

9. On July 18, 2000, United States Letters Patent No. 6,090,410 (the "'410 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '410 patent is currently set to expire on December 2, 2012. The '410 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '410 patent is attached to this Complaint as Exhibit 5.

ANSWER: Apotex admits that United States Patent No. 6,090,410, entitled "Anhydrous Alendronate Monosidum Salt Formulations" was issued by the United States Patent and Trademark Office on July 18, 2000 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '410 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

10. On February 27, 2001, United States Letters Patent No. 6,194,004 (the "'004 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '004 patent is currently set to expire on December 2, 2012. The '004 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '004 patent is attached to this Complaint as Exhibit 6.

ANSWER: Apotex admits that United States Patent No. 6,194,004, entitled "Dry Mix Formulation For Bisphosphonic Acids" was issued by the United States Patent and Trademark

Office on February 27, 2001 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the '004 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

11. On November 30, 1999, United States Letters Patent No. 5,994,329 (the "'329 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates entitled METHOD FOR INHIBITING BONE RESORPTION. The '329 patent is currently set to expire on July 17, 2018. The '329 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '329 patent is attached to this Complaint as Exhibit 7.

ANSWER: Apotex admits that United States Patent No. 5,994,329, entitled "Method For Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on November 30, 1999 to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates, and that a copy of the '329 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

12. On January 18, 2000, United States Letters Patent No. 6,015,801 (the "'801 patent") duly and legally issued to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II entitled METHOD OF INHIBITING BONE RESORPTION. The '801 patent is currently set to expire on July 17, 2018. The '801 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '801 patent is attached to this Complaint as Exhibit 8.

ANSWER: Apotex admits that United States Patent No. 6,015,801, entitled "Method Of Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on January 18, 2000 to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II, and that a copy of the '801 patent is attached to the complaint. Apotex is without knowledge or information

sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

13. On May 1, 2001, United States Letters Patent No. 6,225,294 (the "'294 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II and John Yates entitled METHOD OF INHIBITING BONE RESORPTION. The '294 patent is currently set to expire July 17, 2018. The '294 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '294 patent is attached to this Complaint as Exhibit 9.

ANSWER: Apotex admits that United States Patent No. 6,225,294, entitled "Method Of Inhibiting Bone Resorption" was issued by the United States Patent and Trademark Office on May 1, 2001 to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates, and that a copy of the '294 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

14. Merck is the owner through assignment of the '941, '590, '726, '207, '410, '004, '329, '801 and '294 patents. Merck also owns an approved New Drug Application (NDA No. 20-560) for alendronate sodium tablets that are sold under its trademark FOSAMAX®.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

15. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act. Merck listed the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents in the Orange Book for its FOSAMAX® tablets.

ANSWER: Apotex admits that the '941, '590, '726, '207, '410, '004, '329, '801 and '294 patents are listed in the "Orange Book" for Fosamx® tablets and denies truth of the remaining averments in this paragraph.

16. The FDA granted a six-month period of market exclusivity beyond the patent terms for Merck's FOSAMAX® drug product due to the timely submission and acceptance of

pediatric studies pursuant to 21 U.S.C. § 355a(c). This six-month period is also listed in the Orange Book. The FDA may therefore not approve to market generic versions of Merck's FOSAMAX® tablets until six months after the expiration date of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. The six-month "pediatric exclusivity period" expires on June 2, 2013, for the '941 patent; June 2, 2013, for the '590 patent; December 6, 2015, for the '726 patent; December 6, 2015, for the '207 patent; June 2, 2013, for the '410 patent; June 2, 2013, for the '004 patent; January 17, 2019, for the '329 patent; January 17, 2019, for the '801 patent; and January 17, 2019, for the '294 patent. The FDA also may not approve to market generic versions of Merck's FOSAMAX® tablets until the expiration of all other patents and the subsequent pediatric exclusivity period listed in the Orange Book.

ANSWER: Apotex admits that the Orange Book shows the pediatric exclusivity period for the patents as stated in the averments in this paragraph and Apotex denies the remaining averments in this paragraph.

17. On information and belief, an Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex's ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

ANSWER: Admitted.

18. On information and belief, Apotex filed ANDA No. 077-982 because it seeks to enter the market that FOSAMAX® pharmaceutical products have created due to their benefits and advantages.

ANSWER: Denied, accept to admit that Apotex seeks permission from the FDA to sell a generic version of Fosamax®.

COUNT I

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

20. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '941 patent, before the expiration of the '941 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

21. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '941 patent, it was aware of the existence of the '941 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '941 patent at the time it filed ANDA No. 077-982; otherwise denied.

22. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '941 patent.

ANSWER: Denied.

23. On information and belief, the infringement by Apotex of the '941 patent was and is willful.

ANSWER: Denied.

24. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT II

25. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

26. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '590 patent, before the expiration of the '590 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

27. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '590 patent, it was

aware of the existence of the '590 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '590 patent at the time it filed ANDA No. 077-982; otherwise denied.

28. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '590 patent.

ANSWER: Denied.

29. On information and belief, the infringement by Apotex of the '590 patent was and is willful.

ANSWER: Denied.

30. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT III

31. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

32. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '726 patent, before the expiration of the '726 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

33. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '726 patent, it was aware of the existence of the '726 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '726 patent at the time it filed ANDA No. 077-982; otherwise denied.

34. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '726 patent.

ANSWER: Denied.

35. On information and belief, the infringement by Apotex of the '726 patent was and is willful.

ANSWER: Denied.

36. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT IV

37. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

38. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '207 patent, before the expiration of the '207 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

39. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '207 patent, it was aware of the existence of the '207 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '207 patent at the time it filed ANDA No. 077-982; otherwise denied.

40. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '207 patent.

ANSWER: Denied.

41. On information and belief, the infringement by Apotex of the '207 patent was and is willful.

ANSWER: Denied.

42. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT V

43. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

44. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '410 patent, before the expiration of the '410 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

45. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '410 patent, it was aware of the existence of the '410 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '410 patent at the time it filed ANDA No. 077-982; otherwise denied.

46. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '410 patent.

ANSWER: Denied.

47. On information and belief, the infringement by Apotex of the '410 patent was and is willful.

ANSWER: Denied.

48. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT VI

49. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

50. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '004 patent, before the expiration of the '004 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

51. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '004 patent, it was aware of the existence of the '004 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '004 patent at the time it filed ANDA No. 077-982; otherwise denied.

52. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '004 patent.

ANSWER: Denied.

53. On information and belief, the infringement by Apotex of the '004 patent was and is willful.

ANSWER: Denied.

54. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT VII

55. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

56. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '329 patent, before the expiration of the '329 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

57. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '329 patent, it was aware of the existence of the '329 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '329 patent at the time it filed ANDA No. 077-982; otherwise denied.

58. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '329 patent.

ANSWER: Denied.

59. On information and belief, the infringement by Apotex of the '329 patent was and is willful.

ANSWER: Denied.

60. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT VIII

61. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

62. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or sale of a drug product the use of which is claimed in the '801 patent, before the expiration of the '801 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

63. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '801 patent, it was aware of the existence of the '801 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '801 patent at the time it filed ANDA No. 077-982; otherwise denied.

64. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '801 patent.

ANSWER: Denied.

65. On information and belief, the infringement by Apotex of the '801 patent was and is willful.

ANSWER: Denied.

66. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

COUNT IX

67. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

68. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '294 patent, before the expiration of the '294 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

69. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '294 patent, it was aware of the existence of the '294 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

ANSWER: Apotex admits it was aware of the '294 patent at the time it filed ANDA No. 077-982; otherwise denied.

70. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '294 patent.

ANSWER: Denied.

71. On information and belief, the infringement by Apotex of the '294 patent was and is willful.

ANSWER: Denied.

72. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

ANSWER: Denied.

WHEREFORE, Defendant prays that Plaintiff take nothing from this action and its complaint be dismissed with prejudice, with costs assessed against Plaintiff.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The complaint and each Count thereof fails to state a claim upon which relief can be granted.

Second Affirmative Defense

After a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNTERCLAIM

Counterclaimaint Apotex, Inc. for its counterclaim alleges as follows:

PARTIES AND JURISDICTION

1. Counterclaimant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9.

2. On information and belief, counterdefendant Merck, Inc. ("Merck") is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

3. This Court has subject matter jurisdiction under the patent laws, Title 35 of the U.S. Code; The Declaratory Judgment Act, 28 U.S.C. § 2201; and 28 U.S.C. § 1338.

4. Venue and personal jurisdiction are proper in this district because the counterdefendant, *inter alia*, is subject to personal jurisdiction in this judicial district and has submitted itself to the jurisdiction of this Court.

COUNT I – DECLARATORY RELIEF

5. The '329 and '801 patents are invalid for at least the reasons set forth in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005).

6. Apotex cannot be held liable for infringement of the '941 patent at least because the claims of this patent are limited to a composition comprising excipients consisting essentially of anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate; whereas, Apotex's tablets will not comprise lactose (either anhydrous or hydrous) or croscarmellose sodium, but will comprise as excipients only manitol, microcrystalline cellulose and magnesium stearate.

7. Apotex cannot be held liable for infringement of the '590, '410, and '004 patents at least because the claims of those patents are limited to a tablet comprising a diluent selected

from anhydrous lactose and hydrous fast flow lactose; whereas, Apotex's tablets will not comprise anhydrous lactose or hydrous fast flow lactose.

8. Apotex cannot be held liable for infringement of the '726, '207, and '294 patents at least because the claims of those patents are limited to anhydrous Alendronate sodium; whereas, Apotex's tablets will not contain anhydrous Alendronate sodium.

9. As a consequence of the foregoing, there exists a justiciable controversy as to whether the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are valid and infringed. Apotex is entitled to a declaration that the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents are invalid and/or not infringed.

DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex prays for judgment:

A. Finding the '329 and '801 patents are invalid;

B. Finding the '941, '590, '726, '207, '410, '004, and '294 patents are not infringed;

C. Finding that this is an exceptional case under 35 U.S.C. § 285;

D. Awarding to Apotex its costs, expenses, and reasonable attorney's fees;

E. Awarding such other relief as the Court deems just and appropriate.

JURY DEMAND

Apotex demands trial by jury for all issues triable by jury.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

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Louis T. Walsh
Michael Krol
Welsh & Katz, Ltd.
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Dated: May 9, 2006

By: */s/ Richard L. Horwitz*
Richard L. Horwitz (#2246)
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Hercules Plaza, 6th Floor
1313 N. Market Street
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rhorwitz@potteranderson.com
kdorsney@potteranderson.com

Attorneys for Defendant Apotex, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on May 9, 2006, the attached document was hand delivered on the following person and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF.

Mary B. Graham
James W. Parrett, Jr.
Morris, Nichols, Arsht & Tunnell, LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

I hereby certify that on May 9, 2006, I have Electronically Mailed the attached document to the following non-registered participants:

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I hereby certify that on May 9, 2006, I have Federal Expressed the attached document to the following non-registered participants:

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/s/ Richard L. Horwitz

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728942

EXHIBIT 14
Fully Redacted

EXHIBIT 15
Fully Redacted

EXHIBIT 16

AstraZeneca

FAX COVER SHEET

Legal Department (FOP3)
1800 Concord Pike
P.O. Box 15437
Wilmington, Delaware 19850-5437
USA

PLEASE DELIVER ASAP!!

DATE: 11/6/07

TO: Thomas Irving
Finnegan, Henderson

FROM: **Celeste B. Netta c/o Tom Stevens**

FAX: **202-408-4400**

Number of Pages including cover sheet: 7

Tom – here's another one -- attached is the paragraph IV Certification Letter that we received by federal express today from Apotex Inc. regarding Crestor.

Thanks,
Celeste

APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY
SOCIÉTÉ PHARMACEUTIQUE ENTIÈREMENT CANADIENNE

November 5, 2007

Astrazeneca LP
Wilmington, De 19850-5437

and

Astrazeneca AB
S-151 85
Sodertalje, Sweden

Dear Sirs:

Re: Apotex ANDA for Rosuvastatin Calcium Tablets
Notice Certification of Noninfringement of U.S. Patent Nos. 6,316,460
Offer of Confidential Access to Application

Dear Sirs:

As required by Sections 505(j)(2)(B)(i) and (ii) of the Federal Food, Drug and Cosmetic Act ("Act") (21 U.S.C. § 355(j)(2)(B)(I), (ii)), notice is hereby given to you, that the Food and Drug Administration has received an Abbreviated New Drug Application ("ANDA") submitted by Apotex.

In accordance with 21 C.F.R. § 314.95, the following information is hereby provided:

- The ANDA contains the required bioavailability or bioequivalence data.
- The ANDA number for the application is 79-145.
- The established name for the proposed drug product is Rosuvastatin Calcium tablets. The NDA No. is 02-1366.
- The active ingredient, strength, and dosage form of the product are as follows: rosuvastatin calcium 5, 10, 20 and 40 mg tablets.

I. The Orange Book and Patents

Patent Listed in OB	Expires per the OB	Para. IV Certification
6,316,460	04 Aug. 2020	IV
6,858,618	17 Dec. 2021	
RE 37,314	08 Jan. 2016	

With its ANDA, Apotex has submitted a "paragraph IV certification", pursuant to Sections 505(j)(2)(A)(vii)(IV) of the Act (21 U.S.C. § 355(j)(2)(A)(vii)(IV)), that its proposed tablets will not infringe the **6,316,460** patent.

As to the RE '314 patent and the '618 patent, Apotex is not certifying under Paragraph IV to these patents.

In accordance with 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §§ 314.95(c)(6)(i), (ii), the factual and legal bases for the paragraph IV certification and the statement that the patent will not be infringed is set forth below.

II. Legal Standards

Any patent infringement analysis consists of a two-step process: determining the scope of the claims, a legal issue for the Court, and comparing the accused device to the claims, a factual question. *Carroll Tough, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576 (Fed. Cir. 1993); *see also cybor Corp. v. FAS Techs., Inc.*, 238 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc) (claim construction is an issue of law, subject to *de now* review). A claim may be infringed either: (1) literally; or, (2) under the judicially created doctrine of equivalents.

Literal infringement requires a patentee to prove that every limitation for the asserted claim is literally met by the accused device. *E nercon v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998); *Amhil Enters. Ltd. V. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996) (literal infringement occurs when "the properly construed claim reads on the accused devise exactly"). The failure to meet even a single element within a claim mandates a finding that the accused product does not infringe the patent. *Laitram corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991).

The Supreme Court in *Warner-Jenkinson* held that even in instances where the claims do not read literally on the accused product or method, the patentee may look to the doctrine of equivalents to prove infringement. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002). Infringement

under the doctrine of equivalents requires the patentee to show, for each claim asserted, the presence of each and every claim element or its substantial equivalent in the accused device. *Warner-Jenskinson*, 520 U.S. at 40 (applying the doctrine of equivalents analysis to the individual claim limitations, not the invention as a whole); *Wolverine World Wide, Inc. v. Nike, Inc*, 38 F.3d 1192, 1199 (Fed. Cir. 1994).

III. Analysis of the Patents and the Apotex Product

The claims of US Patent No. 6,316,460 are limited to a composition comprising a tribasic phosphate salt in which the cation is multivalent.

There will be no infringement because our tablets will not comprise a tribasic phosphate salt in which the cation is multivalent or an obvious equivalent. The use of the multivalent cation was repeatedly stressed during prosecution. See e.g., Office Action Response, dated 19 June 2001, pg. 10 ("However, this characterization of the present claims overlooks the further limitation in all of the present claims that the tribasic phosphate salt has a multivalent cation."); also page 13 ("summary, the present claims are directed toward a composition comprising [compound] or a pharmaceutically acceptable salt thereof as the active ingredient, and a "tribasic phosphate salt in which the cation is multivalent." (See, e.g., Claim 1)."); see also Reasons for Allowance, pg. 2 as part of the Notice of Allowance.

Apotex affirmatively states that it may have further basis, in addition to those stated above, supporting its noninfringement and/or invalidity positions under 35 U.S.C. §§ 101 *et seq*, (including §§ 102(a), (c)-(g) and § 112), and further that additional basis bearing on the validity, noninfringement, and/or enforceability of the patents and to which Apotex is required to certify, may develop in the event of litigation between the parties. Apotex expressly reserves the right to assert additional defenses and grounds bearing on the validity, noninfringement, and/or enforceability of the patent in the even of litigation between the parties.

Receipt of this notice begins the 45-day period provided for in Section 505(j)(5)(B)(iii) of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. The ANDA will be amended with a copy of the return receipt for this notice, as required by 21 C.F.R. § 314.95(e).

IV Offer of Confidential Access to Application

Pursuant to 21 U.S.C. § 355 (j)(5)(C), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003), this notice letter includes an Offer of Confidential Access to Application. As required by § 355(j)(5)9C)(i)(III), and pursuant to certain

restrictions described below, Apotex offers to provide you with confidential access to certain information from its ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought.

Section 355(j)(5)(C)(i)(III) allows Apotex to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protection order been entered for the purpose of protecting trade secrets and other confidential business information." That provision also grants Apotex the right to redact its ANDA in response to a request for Confidential Access under this offer.

As permitted by statute, Apotex imposes the following terms and restrictions on its Offer of Confidential Access:

1) Apotex will permit confidential access to certain information from its proprietary ANDA to attorneys from one (1) outside law firm representing you; provided, however, that such attorneys do not engage, formally or informally, in patent prosecution for you. Such information (hereinafter, "Confidential Apotex Information") shall be marked with the legend "CONFIDENTIAL".

2) The attorneys from the outside law firm representing you shall not disclose any Confidential Apotex Information to any other person or entity, including your employees, outside scientific consultants, and/or other outside counsel retained by you, without the prior written consent of Apotex.

3) As provided by § 355(j)(5)(C)(i)(III), your outside law firm shall make use of the Confidential Apotex Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought and for no other purpose. By way of example only, the Confidential Apotex Information shall not be used to prepare or prosecute any further or pending patent application by you, or in connection with any filing to, or communication with, the FDA relating to Apotex' ANDA. Your outside law firm agrees to take all measure necessary to prevent unauthorized disclosure or use of the Confidential Apotex Information, and that all Confidential Apotex Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access. Your outside law firm further agrees never to use Confidential Apotex Information, directly or indirectly, in competition with Apotex, nor will it allow any other person or entity to do so.

4) The Confidential Apotex Information disclosed is, and remains, the property of Apotex. By providing the Confidential Apotex Information, Apotex does not grant you and/or your law firm any interest in or license for the Confidential Apotex Information.

5) Your law firm shall, within thirty-five (35) days from the date that it first receives the Confidential Apotex Information, return to Apotex all Confidential Apotex Information and any copies thereof. Your law firm shall return to Apotex all Confidential Apotex Information before any infringement suit is filed by your, if suit is commenced before this 45-day period expires. In the event that you opt to file suit, none of the information contained in or obtained from any Confidential Apotex Information that Apotex provides will be included in any publicly-available complaint or other pleading.

6) Nothing in this Offer of Confidential Access shall be construed as an admission by Apotex regarding the validity, enforceability, and/or infringement of any U.S. Patent. Further, nothing herein shall be construed as an agreement or admission by Apotex with respect to the competency, relevance, or materiality of any such Confidential Apotex Information, document, or thing. The fact that Apotex provides Confidential Apotex Information upon your request shall not be construed as an admission by Apotex that such Confidential Apotex Information is relevant to the disposition of any issue relating to any alleged infringement of the patent, or to the validity or enforceability of the patent.

7) The attorneys from your outside law firm will acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential Apotex Information. Such written acknowledgement shall be provided to Apotex.

8) This Offer of confidential Access shall be governed by the laws of the State of Illinois.

Section 355(j)(5)(C)(i)(III) of the Act provides that any request for access that you make under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in [this] offer of confidential access" and that the "restrictions and other terms of [this] offer of confidential access shall be considered terms of an enforceable contract." Thus, to the extent that you request access to Confidential Apotex Information, you necessarily accept the terms and restrictions outlined above. Written notice requesting access under this Offer of Confidential Access should be made to:

Mr. Shashank Upadhye, Esq.
Vice President, Global Intellectual Property
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9
Telephone: (416) 401-7701
Fax: 416-401-3808

By providing this Offer of Confidential Access to Application, Apotex maintains the right and ability to bring a Declaratory Judgment action under 28 U.S.C. §§ 2201 *et seq.*, pursuant to 21 U.S.C. § 355(j)(5)(C).

* * *

V. Service of Process and Courtesy Copies

The following person is authorized to accept service of process on behalf of Apotex:

Tammy McIntire
Apotex Corp.
2400 N. Commerce Parkway
Weston, FLA 33326
Tel: (954)384-8007
Fax: (954)385-8518

As a matter of professional courtesy, please send a copy of any complaint filed to Shashank Upadhye, Esq. at:

Mr. Shashank Upadhye, Esq.
Vice President, Global Intellectual Property
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9
Telephone: (416) 401-7701
Fax: 416-401-3808

Yours very truly,
APOTEX INC.

Bernice Tao
Director, Regulatory Affairs US

EXHIBIT 17
Fully Redacted

EXHIBIT 18

WELSH & KATZ, LTD.

Attorneys at Law

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FACSIMILE (312) 655-1501

www.welshkatz.com

April 17, 2008

VIA E-MAIL

Mr. Nathan A. Evans
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, NW
Washington, DC 20001-4413

Re: AstraZeneca et al. v. Apotex Inc. and Apotex Corp.
Case No. 07-809-JJF, D. Del.
Our file: 8898/102933

Dear Nathan,

We are writing to clarify a statement made in our letter to you yesterday. In that letter we stated that in the time frame of 2003 – 2006, sales representatives for Apotex Corp. made occasional sales visits with its only direct customer in Delaware, Happy Harrys, and that these visits took place approximately once or twice a year. Since sending you that letter, we have obtained more detailed information about these sales visits to Happy Harrys in Delaware. In particular, only 3 sales visits were made to Delaware by an Apotex Corp. sales representative during the past five years, and the visits took place in 2003, 2004, and 2006.

Very truly yours,

WELSH & KATZ, LTD.

Laurie A. Haynie

Enclosures
cc: Robert B. Breisblatt
J. Aron Carnahan
Richard L. Horwitz
David E. Moore

EXHIBIT 19

2007 WL 1290291 (F.D.C.H.)
2007 WL 1290291 (F.D.C.H.)

Testimony
May 02, 2007

House of Representatives
Energy and Commerce
Commerce, Trade, and Consumer Protection

Appliance Efficiency Standards

Statement of Barry **Sherman**
Chief Executive Officer
Apotex, Inc.
Committee on House Energy and Commerce
Subcommittee on Commerce, Trade, and Consumer Protection
May 02, 2007
Introduction
Chairman Rush, Ranking Member Steams, Members of the Subcommittee, thank you very much for the opportunity to testify before you on anti-competitive patent settlements between brand and generic pharmaceutical companies. My name is Bernard **Sherman**. I am the CEO and Chairman of **Apotex** Inc. **Apotex** is the largest Canadian pharmaceutical manufacturer. We are also one of the largest generic drug manufacturers in the world. In the United States, we are the 7'h largest generic drug manufacturer measured by sales. Our U.S headquarters is located in Weston, Florida. We also have a distribution center in Indianapolis, Indiana.
Apotex is pleased to testify today in support of HR 1902. **Apotex** shares your view that settlements in which brand and generic pharmaceutical manufacturers thwart consumer access to generic drugs through collusive agreements should be unlawful. Such settlements are the antithesis of what was intended by Congress in the Hatch-Waxman provisions. **Apotex** applauds you for your introduction of this legislation and your leadership on this important consumer issue. We hope you find the recommendations we will put forward today, which we recognize fall under the jurisdiction of the Energy and Commerce Committee's Health Subcommittee, helpful as you and your colleagues in both subcommittees continue your work to ensure consumers have timely access to quality, affordable generic medicines.
At **Apotex**, we believe generic companies should endeavor to bring generics to market at the earliest possible time, and that the legislative and regulatory framework should facilitate, not obstruct, early generic entry. Our record in advocating for such a public policy framework, from our support for a district court

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trigger for exclusivity rather than an appellate trigger, our pursuit of declaratory judgment actions, our efforts in the courts to vacate anti-competitive settlements, our pursuit of infringement verdicts even where there is no guaranteed benefit to us, and our opposition to patent settlements, is unique and unmatched among generic manufacturers.

As one example, about 5 weeks ago, **Apotex** succeeded in invalidating Pfizer's patent for amlodipine besylate, sold by Pfizer as Norvasc . **Apotex** undertook this battle despite the fact Mylan, and not **Apotex**, was the first to file with a paragraph iv certification. The result of our investment, our work and our victory was that Mylan, and not **Apotex** was then immediately able to launch a generic amlodipine product. As a consequence, consumers are now saving hundreds of millions of dollars, Mylan is garnering hundreds of millions of dollars of profits that rightfully should have gone to **Apotex**, while **Apotex** receives no benefit whatsoever, and is left only with a large loss on the investment in the litigation. This is a perverse outcome of a system that rewards only the first to file, even if the first to file does not litigate and win, and ignores the needs of a subsequent filer who is prepared to fight to win. It is this flaw in the system that is the root of the settlement problem.

As another example, **Apotex** has sued to invalidate the settlement agreements between Cephalon and four generic first-filers. Under the settlement agreements, the generics have agreed to abandon the patent challenge and defer launch until shortly before patent expiry. **Apotex** is prepared to carry on the patent challenge, just as it did for amlodipine, but again will get nothing in return, because of two anticompetitive aspects of settlements. The first is that the first filers will continue to hold the180 Hatch-Waxman exclusivity, despite the fact that they have settled. Thus, even if **Apotex** wins, it will still be unable to sell. The second is that the settlements invariably contain a 'poison pill' provision, whereby market entry of the first filers will be accelerated if a subsequent filer, such as **Apotex**, continues to litigate and wins. This means that, if **Apotex** continues to litigate and wins, the result will again be that **Apotex** will continue to be held off the market, while the first filers, who agreed not to launch for years, will be able to launch and thus take all of the benefit properly earned by **Apotex**, again leaving **Apotex** with nothing but costs.

Apotex very much wants to continue to fight for the interests of consumers, as intended by the Hatch-Waxman provisions. However, it should be clear that we will be unable to continue to do what is right, unless Congress addresses the essential problems. Two things are sorely needed:

1.An amendment that gives shared (if not sole) exclusivity to a generic challenger who, although not first to file with a. paragraph iv certification, is first to succeed in addressing the listed patents.

2. Amendments to stop settlement agreements from denying any benefit to a subsequent filer who continues to fight.

Specifically:

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i)a generic first filer who enters into any settlement agreement should immediately forfeit its exclusivity; and
ii)a generic first filer who agrees to defer launch should not be permitted to then accelerate launch as a result of a win by a subsequent filer who continues to litigate.
Having first filer settlements result in the forfeiture of exclusivity is crucial to ensuring that the system functions the way Congress originally intended. Allowing first filers to preserve exclusivity when they settle for market entry only months before patent expiry will result in a system in which every early generic entry will forever be capped at only months before patent expiry. There is no doubt, Mr. Chairman, that, if permitted to get away with it, the first-filer and brand company will ALWAYS settle for generic entry only slightly before patent expiry, maintaining almost all of the life of every monopoly, even when the patents are clearly invalid and or not infringed. Consumers are much better off with a system that allows for the possibility of generic entry years rather than just months earlier. Indeed, Congress' intent in passing the Hatch-Waxman regime was to create a framework under which generics were incentivized -- for the benefit of consumers to break, not preserve, patents that are invalid or not infringed.
I would also emphasize, Mr. Chairman, that we are not proposing that settlements be barred. We do not think they should be. If a first filer thinks slightly earlier generic entry is a good deal, it should take that deal. But it should not be permitted to stand in the way of another generic who thinks it can get to market even earlier, and is willing to take up the patent fight. Otherwise, benefits that might have been won for consumers will never be realized.
Mr. Chairman, **Apotex** commends you for including in HR 1902 a provision that would correct the declaratory judgment problem -- a key loophole that contributes to the 'bottleneck' problem. These bottlenecks arise when first to file generic companies conspire with their brand counterparts to block the market and delay generic competition.
The inability of subsequent generic filers to get a declaratory judgment ('DJ') helps to sustain the monopoly. Current law requires subsequent filers to successfully litigate the same universe of patents to which the first filer has certified. To ensure that market entry remains indefinitely blocked, brand companies simply do not sue subsequent generic filers.The only avenue left for a subsequent filer is to pursue a DJ action. Unfortunately, the courts have routinely dismissed efforts to get a DJ, on the basis that the generic lacks standing to sue. It appeared that the decision of the Supreme Court in the MedImune case might resolve this problem. However, patentees have come up with a new gimmick. In addition to not suing, they now give covenants not to sue.
As an example, **Apotex** has been seeking a DJ to trigger the exclusivity on alendronate, sold by Merck under the tradename Fosamaxr. Merck responded with a covenant not to sue, and despite the Supreme Court's decision in MedImune, the District Court has

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again held that **Apotex**' motion for a DJ is not justiciable because of the covenant not to sue. The situation is preposterous. A covenant not to sue has no meaning, because **Apotex**' market access will remain blocked by the exclusivity that **Apotex** cannot trigger.
HR 1902 corrects the DJ problem by making both the dismissal of a DJ action for lack of subject matter jurisdiction and the execution of a covenant not to sue triggering events for the first filer's exclusivity.
Apotex strongly supports the enactment of this provision. However, we must caution that even this provision will be ineffective, unless the problem of anti-competitive settlements is adequately addressed. If and when your proposed provision to fix the DJ problem is enacted, the result will be that the patentee will invariably sue the subsequent filer, thereby subjecting the subsequent filer to the enormous cost of litigation. No subsequent filer will be able to justify the cost, whenever there has been a settlement wherein the first filer has agreed to delay launch, while maintaining exclusivity, as any subsequent filer who continues to litigate can get no reward. Anti-consumer patent settlements will continue unabated.
HR 1902 includes a provision that would ban so called 'reverse payments' -- from a brand to a generic company settling a patent infringement case. The intuitive reaction shared by almost all is that reverse payments are unethical and wrong. However, **Apotex** believes that this issue is a 'red herring' and that outlawing reverse payments, if not coupled with other amendments, will have no significant impact on the number of settlements or their anticompetitive impact, but will simply reduce the cost of such agreements for patentees. This can be understood from the following analysis.
A settlement typically includes a provision that the first generic applicant will be licensed to enter the market during the last year or less prior to patent expiration. The significant value for the first generic applicant is the 180 day exclusivity. Litigation is almost always uncertain as to outcome. If the generic litigates, there is a risk of losing and ending up with nothing. Hence, it is inevitable that it will always make more sense for a generic to settle for exclusivity during the last months of patent life rather than to litigate in the hope of winning and getting earlier entry. The reason that generics have been able to negotiate for 'reverse payments' in addition to market entry during the last months is that the agreement is enormously valuable to the patentee. 'The patentee keeps the monopoly for all but the last months, so the benefit to the patentee is generally enormously greater than to the generic. The generic thus takes the position that it is not willing to settle for only a generic monopoly during the last months, and the patentee is always willing to provide a further benefit to the generic through a 'reverse payment'. It may appear that, if such reverse payments are made illegal, the generic company will simply demand that the patentee allow it to enter the market even earlier than the last months of patent life as a substitute for

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the banned payment. However, that fails to take into account that earlier entry for the generic has very little additional value, because the exclusivity will terminate and other generics will enter the market 180 days after first sale by the first generic. It follows that making reverse payments illegal is unlikely to have any substantive effect on settlements, that generics will still settle for guaranteed market entry during the last months of patent life, and the only effect, if any, will be that the cost of settling will be reduced for the patentee, with no benefit for consumers.

As mentioned earlier, in **Apotex's** view, it is critical to recognize that the primary anticompetitive aspects of settlements are those that eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry.

We thus urge the Subcommittee to work for legislation that includes all of the following features:

1.A provision that makes both dismissal of a DJ action for lack of jurisdiction and execution of a covenant not to sue triggering events for the first filer's exclusivity, as now proposed in HR 1902.

2.An amendment that gives shared (if not sole) exclusivity to a generic challenger who, although not first to file with a paragraph iv certification, is first to succeed in addressing the listed patents.

3. Amendments to stop settlement agreements from denying any benefit to a subsequent filer who continues to fight.

Specifically:

a.a generic first filer who enters into any settlement agreement should immediately forfeit its exclusivity; and

b.a generic first filer who agrees to defer launch should not be permitted to then accelerate launch as a result of a win by a subsequent filer who continues to litigate.

As aforesaid, we believe that there is a fundamental flaw in a system that rewards only the first to file, regardless of whether or not the first to file continues to litigate for the earliest possible market entry, and that, conversely, denies any reward for the generic that does litigate and wins. To ensure timely consumer access to generic competition, this fundamental flaw must be fixed.

Year after year, **Apotex** has tirelessly litigated to bring products to market, as we believe was intended by Congress. We want to continue down that path, and urge Congress to make it possible by addressing all of these issues.

Adopting this approach will bring a swift and just end to the bottleneck problem. This approach would preserve the right of all companies to settle litigation -- a right that should be preserved. What it would not allow is the continued perversion of the 180 day exclusivity period -- an award Congress intended to incentivize generic companies to open markets early, not block them.

Conclusion

Thank you very much for inviting **Apotex** to share our views with you and the Members of this Subcommittee on this issue. Please

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know that **Apotex** stands ready to assist you and your colleagues in this Subcommittee and the Health Subcommittee in any capacity in which you may call on us.We hope that our insight has helped and will help in arriving at legislation that will work as intended by Congress for the benefit of consumers.

BARRY **SHERMAN**

Chief Executive Officer

Apotex, Inc.

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END OF DOCUMENT

EXHIBIT 20

Business

Face value

Generic gadfly

Apr 11th 2002

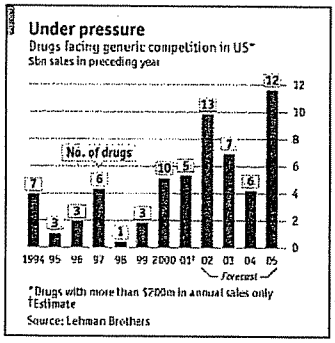
From *The Economist* print edition

Barry Sherman and his generic-drug company, Apotex, have put Big Pharma in a tizzy

TO HIS supporters, Barry Sherman, chairman of Apotex, a Canadian maker of generic drugs, is an indefatigable champion of low-cost drugs against profiteering patent-holders, as well as a generous philanthropist whose millions fund universities and hospitals. To his detractors, Mr Sherman is a shameless copy-cat who seeks to misappropriate the hard-won intellectual property of research-oriented drug companies. Yet Apotex—with only 4,200 employees and C$600m ($376m) in annual sales—is a midget compared with the giants of the pharmaceutical industry. So why is Mr Sherman so controversial?

In a single word: litigation. Apotex is famous for suing anybody who tries to stop it selling a generic version of a bestselling drug. No matter that the inventors' patents may have years to run; Mr Sherman is a master at picking holes in such claims, and then pursuing his interests in court. His company is embroiled in almost 100 lawsuits and spends more than $10m a year in legal fees.

Although Mr Sherman's tactics are certainly aggressive, many of Apotex's battles are simply occupational hazards. A piece of American legislation known as the Waxman-Hatch act encourages generic-drug companies by rewarding the first copier off the mark with six months' market exclusivity once a patent expires. But patent-holders are more reluctant than ever to lose control over their drugs, given that a record number of the industry's blockbuster drugs now face generic competition (see chart).



This is why brand-name drug companies are striking back, filing additional patents to extend their grip, and then suing any generic challengers for patent infringement. Such retaliation is encouraged by a twist in the law that triggers a delay in the regulatory approval of any generic drug of up to 30 months if a lawsuit has been filed. At this point, Apotex usually countersues a patent-holder for damages, and so the destructive dancing continues. American lawmakers are now considering reforming Waxman-Hatch to put a stop to the ball.

Government is, however, another of Mr Sherman's targets. Apotex routinely takes on Canada's federal health ministry for failing to approve its generics, or the provincial governments for restricting reimbursement of its drugs. Mr Sherman speaks warmly of the 1970s, when he started Apotex and the government's patent policy favoured domestic firms. Now he complains that the politicians are in hock to foreign drug giants.

Although Mr Sherman likes to present Apotex as a plucky underdog, some recent events suggest otherwise. Six months ago, Apotex managed to sell the Canadian government C$1.5m-worth of ciprofloxacin, an antibiotic to treat anthrax, even though the patent still belongs to Germany's Bayer. The ensuing scandal made the government look panicky and reinforced Mr Sherman's reputation as a wily operator.

Imitation, not flattery

While they may deplore his tactics, many of Mr Sherman's opponents grudgingly admire his stamina. In January, Apotex lost a legal battle against Bayer over a cardiovascular drug, but only after years of brawling in the courts. Such persistence often pays. Last year, Prozac went off-patent after a fierce legal battle between its inventor, Eli Lilly, and Barr Laboratories, a generic firm. By the end of the year, Barr had raked in $312m in sales of copy-cat Prozac. Almost half of that was shared with Apotex, which first came up with a generic version of the drug and helped to break Eli Lilly's hold. Mr Sherman has a 25% stake in Barr.

On top of his windfall from Barr, Mr Sherman owns 90% of Apotex, which in turn has a majority stake in Cangene, one of Canada's few profitable biotechnology firms. All this makes Mr Sherman one of Canada's wealthiest men, worth an estimated C$2.5 billion. But he is happier earning money than spending it. When his wife replaced his ancient Cadillac with a brand new BMW as a birthday surprise, he had the gift towed away and his old car returned.

Mr Sherman's obsessive ambition is to turn Apotex into one of the world's leading drug makers by 2020. The company already sells more than 180 drugs in 115 countries, but Mr Sherman hopes to expand further into Europe and in America, where generics now account for more than 40% of all prescriptions. At the moment, America makes up only one-tenth of Apotex's sales. Although consolidation is sweeping through the generic industry, Mr Sherman plans to keep Apotex independent and in private hands.

But this may prove increasingly hard as the company dabbles in novel drugs. Not only is discovering and developing new drugs a lot more expensive than reformulating existing ones; selling them also requires costly marketing to doctors and patients, rather than cheaper marketing to pharmacists.

Apotex spends a mere C$115m a year on research and development, mainly on generic products. Its most recent foray into making original drugs—deferiprone, a blood-disorder medicine—made headlines when its chief clinical investigator, Nancy Olivieri, claimed that the treatment was doing more harm than good, and that Apotex was putting prestige ahead of patients.

Deferiprone is now on sale in Europe, although Dr Olivieri is challenging its approval. Mr Sherman plans to apply for regulatory approval in America and Canada soon, and Apotex also has two successors in the works. Despite his attacks on brand-name drug makers, Mr Sherman is willing to appropriate their strategies to extend the patents on his own drugs when the time comes. With typical candour, he says that the only lesson he has learned from the deferiprone drama is not to deal with "mentally imbalanced" researchers. Not surprisingly, he and Dr Olivieri are suing each other in court.

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EXHIBIT 21

Apotex patent litigation 2002 - current: Search Result List

Court	Docket Number	Docket Title	Patent Party	Filed	Date Retrieved	Active or Closed	Identification
U.S. District - California Central	8:04cv859	Dey LP v. Apotex Inc et al	Apotex Corp	07/21/2004	08/20/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - California Central	2:04cv4483	Dey LP v. Apotex Inc et al	Apotex Corp	06/22/2004	08/20/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - California Northern	3:05cv2116	Roche Palo Alto LLC et al v. Apotex, Inc et al	Apotex Corp A Delaware Corporation	05/24/2005	10/11/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:07cv809	Astrazeneca Pharmaceuticals LP et al v. Apotex Inc et al	Apotex Corp	12/11/2007	02/12/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:07cv278	Allergan Inc v. Apotex Inc et al	Apotex Corp	05/21/2007	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:07cv792	Sanofi-Aventis et al v. Apotex Inc et al	Apotex Corp	12/06/2007	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:07md1866	In Re: Brimonidine Patent Litigation	Apotex Corp	08/21/2007	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:07cv204	Medpointe Healthcare Inc v. Apotex Inc et al	Apotex Corp	04/17/2007	02/09/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:06cv230	Merck & Co Inc v. Apotex Inc	Apotex Inc	04/07/2006	02/08/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:08cv65	Boehringer Ingelheim Pharmaceuticals Inc v. Apotex Inc et al	Apotex Corp	01/31/2008	02/04/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:06cv164	Medpointe Healthcare Inc v. Apotex Inc et al	Apotex Corp	03/10/2006	01/24/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Delaware	1:07cv779	Senju Pharmaceutical Co Ltd et al v. Apotex Inc et al	Apotex Corp	11/29/2007	01/16/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District	1:07cv549	Purdue Pharma	Apotex Corp	09/12/2007	01/07/2008	Closed	NOS: (830)

- Delaware		LP et al v. Apotex Inc et al					Patent; Cause: Patent Infringement
U.S. District - Delaware	1:03cv990	Apotex Inc, et al v. Pfizer Inc, et al	Apotex Corp	10/29/2003	06/29/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - District of Columbia	1:05cv691	Teva Pharmaceutical Industries, Ltd v. Hikal Group, Ltd Et A	Apotex Corp Counter	04/06/2005	05/31/2005	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - District of Columbia	1:04cv1157	Zambon Group SPA v. Teva Pharmaceuticals, Ltd	Apotex Corp	07/08/2004	04/20/2006	Closed	NOS: (830) Patent; Cause: Declaratory Judgement
U.S. District - Florida Middle	2:08cv98	Boehringer Ingelheim Pharmaceuticals, Inc v. Apotex Inc Et A	Apotex Corp	02/04/2008	02/07/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Florida Middle	8:08cv213	Apotex Inc v. Astrazeneca Pharmaceuticals LP et al	Apotex Inc	01/31/2008	02/01/2008	Active	NOS: (830) Patent; Cause: Declaratory Judgment
U.S. District - Florida Southern	0:07cv61800	Sanofi-Aventis et al v. Apotex, Inc et al	Apotex Corp	12/10/2007	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Illinois Northern	1:08cv827	Nycomed GMBH et alV Apotex Inc et al	Apotex Corp	02/07/2008	02/12/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Illinois Northern	1:06cv1308	Janssen Pharmaceutica, NV et al v. Apotex, Inc	Apotex Inc A Canadian Corporation	03/09/2006	02/13/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Illinois Northern	1:07cv4050	Ortho-McNeil Pharmaceutical, Inc v. Apotex, Inc	Apotex Inc	07/18/2007	02/08/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Illinois Northern	1:06cv2494	Abbott Laboratories v. NU-Pharm, Inc et al	Apotex Corp A Delaware Corporation	05/03/2006	01/21/2007	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Illinois Northern	1:04cv7312	Apotex Corp v. Merck & Co Inc	Apotex Corporation	11/12/2004	07/20/2007	Closed	NOS: (830) Patent; Cause: Federal Question
U.S. District - Illinois Northern	1:05cv3714	Abbott Laboratories v. NU-Pharm, Inc	Apotex Corp	06/24/2005	01/21/2007	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Illinois Northern	1:03cv2028	Daiichi Phar Co Ltd, et al v. Apotex Inc	Apotex Inc	03/20/2003	09/30/2004	Closed	NOS: (830) Patent; Cause: Patent Infringement

U.S. District - Indiana Southern	1:06cv1642	Alcon Manufacturing, Ltd et al v. Apotex Inc et al	Apotex Corp	11/15/2006	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	2:07cv248	Teva Pharmaceutical Industries Ltd et al v. Apotex, Inc Et A	Apotex Corp	01/12/2007	02/13/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	2:07cv3770	Eli Lilly and Company v. Actavis Elizabeth LLC	Apotex Inc	08/09/2007	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	2:07cv4417	Hoffman-La Roche Inc v. Apotex Inc et al	Apotex Corp	09/14/2007	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:07cv1000	Otsuka Pharmaceutical Co, Ltd v. Sandoz, Inc	Apotex Corp Civil 07 1346 Consol	03/02/2007	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:07cv1346	Otsuka Pharmaceutical Co, Ltd v. Apotex Corp et al	Apotex Corp	03/23/2007	02/13/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	2:03cv937	Daiichi Pharmaceutic, et al v. Apotex Inc	Apotex Corp	03/04/2003	01/28/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	2:07cv4937	Acorda Therapeutics, Inc v. Apotex Inc et al	Apotex Corp	10/11/2007	01/30/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:06cv5789	Merck & Co, Inc v. Apotex Inc et al	Apotex Corporation	12/04/2006	01/22/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	2:06cv1020	Janssen Pharmaceutical, NV et al v. Apotex, Inc	Apotex Inc	03/07/2006	10/15/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:07cv4897	Teva Pharmaceutical Industries Ltd et al v. Apotex, Inc Et A	Apotex Corp	10/10/2007	11/25/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:02cv848	Ranbaxy Pharm, et al v. Apotex, Inc	Apotex Inc	02/28/2002	01/03/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:07cv5514	Teva Pharmaceutical Industries Ltd et al v. Apotex, Inc Et A	Apotex Corp	11/15/2007	01/02/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District	2:06cv1153	Apotex Inc et al	Apotex Corp	03/10/2006	04/25/2007	Closed	NOS: (830)

- New Jersey		v. Pharmaceutical Resources, Inc et al					Patent; Cause: Patent Infringement
U.S. District - New Jersey	2:06cv2935	Janssen Pharmaceutica, NV et al v. Apotex, Inc	Apotex Inc	06/27/2006	12/05/2006	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:03cv3860	Ferring BV, et al v. Apotex, Inc	Apotex Inc	08/14/2003	10/24/2006	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:05cv4083	Ferring BV v. Apotex, Inc et al	Apotex Inc	08/17/2005	04/11/2006	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New Jersey	3:06cv5791	Merck & Co, Inc v. Apotex Inc et al	Apotex Corporation	12/04/2006	04/23/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Eastern	1:02cv1604	Apotex, Inc et al v. Eon Labs Manufacturing, Inc	Apotex Inc	03/14/2002	02/15/2005	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	1:02cv2255	Sanofi-Synthelabo, et al v. Apotex Inc, et al	Apotex Corp	03/21/2002	02/13/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	1:02cv3672	Sanofi-Synthelabo, et al v. Dr Reddy's Labs, et al	Apotex Corp	05/14/2002	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	1:02cv8917	Novartis Pharma, et al v. Apotex Corporation, et al	Apotex Corporation	11/08/2002	02/13/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	1:05cv2659	Bristol-Myers Squibb Company et al v. Apotex, Inc et al	Apotex Corp	03/08/2005	02/13/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	1:06cv5540	Teva Pharmaceutical Works Ltd et al v. Apotex, Inc et al	Apotex Corp	07/21/2006	02/13/2008	Closed	NOS: (830) Patent; Cause: Declaratory Judgement
U.S. District - New York Southern	1:04cv2312	Bristol-Myers Squibb Company et al v. Teva Pharmaceuticals USA, Inc Et A	Apotex Corp	03/23/2004	02/13/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	1:05cv3855	Novartis AG et al v. Apotex Inc et al	Apotex Corporation	04/15/2005	01/11/2008	Closed	NOS: (830) Patent; Cause: Patent Infringement

U.S. District - New York Southern	1:07cv8002	Purdue Pharma LP et al v. Apotex Inc et al	Apotex Corp	09/12/2007	01/12/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	1:06cv5571	Unigene Laboratories, Inc et al v. Apotex, Inc.et al	Apotex Corp	07/24/2006	01/10/2008	Active	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	2:02cv2255	Sanofi-Synthelabo, et al v. Apotex Inc, et al	Apotex Corp	03/21/2002	06/20/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - New York Southern	1:04cv2539	Apotex, Inc et al v. Pfizer, Inc	Apotex Corp	04/01/2004	04/04/2007	Closed	NOS: (830) Patent; Cause: Declaratory Judgement (Insurance)
U.S. District - New York Southern	1:04cv2922	Apotex Inc et al v. Bristol-Myers Squibb Co	Apotex Corp	04/15/2004	03/30/2007	Closed	NOS: (830) Patent; Cause: Declaratory Judgement (Insurance)
U.S. District - New York Southern	1:05cv3965	Apotex, Inc et al v. Sanofi-Aventis et al	Apotex Corp	04/20/2005	04/02/2007	Closed	NOS: (830) Patent; Cause: Declaratory Judgement
U.S. District - Pennsylvania Eastern	2:02cv1484	Smithkline Beecham v. Geneva Pharmaceutica, et al	Apotex Corp	03/22/2002	07/23/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Pennsylvania Eastern	2:02cv7119	Biovail Laboratories, Inc v. Torpharm, Inc	Apotex Inc	09/03/2002	02/28/2006	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Pennsylvania Eastern	2:02cv8493	Smithkline Beecham, PLC v. Alphapharm Pty, Ltd et al	Apotex Corporation	11/15/2002	08/16/2007	Closed	NOS: (830) Patent; Cause: Patent Infringement
U.S. District - Virginia Eastern	3:06cv698	Apotex, Inc v. Novartis AG et al	Apotex Inc	10/19/2006	02/11/2008	Closed	NOS: (830) Patent; Cause: Patent Non-Infringement - Declaratory Judgment
U.S. District - Virginia Eastern	2:07cv40	Apotex, Inc v. Glaxo Group Limited	Apotex Inc	01/24/2007	08/10/2007	Closed	NOS: (830) Patent; Cause: Declaratory Judgment

Search Title Untitled Search 2/13/2008

Client Matter Code 10305.8050-00000/6203livingst

Common

Litigants	apotex

U.S. District Courts (Civil)

Courts	ALL
Case Types	ALL,Civil
Nature Of Suit	Patent (830)
Start Date	12/31/2001
End Date	2/13/2008
Case Status	ALL

EXHIBIT 22

Westlaw.
125 Fed.Appx. 987
125 Fed.Appx. 987, 2005 WL 821393 (C.A.Fed.)
(Cite as: 125 Fed.Appx. 987, 2005 WL 821393)

Apotex Inc. v. Pfizer, Inc.
C.A.Fed.,2005.
This case was not selected for publication in the Federal Reporter.NOTE: Pursuant to Fed.Cir.R. 47.6, this order is not citable as precedent. It is public record.Please use FIND to look at the applicable circuit court rule before citing this opinion. Federal Circuit Rule 47.6. (FIND CTAF Rule 47.6.)
United States Court of Appeals,Federal Circuit.
APOTEX INC. (**formerly** known as **TorPharm**, Inc.) and **Apotex** Corp., Plaintiffs-Appellants,
v.
PFIZER INC. and Warner-Lambert Company (now known as Warner-Lambert Company LLC), Defendants-Appellees.
No. 04-1463.

DECIDED: April 11, 2005.

Before MAYER, Circuit Judge, PLAGER, Senior Circuit Judge, and GAJARSA, Circuit Judge.

PER CURIAM.
***1** Apotex Inc. and Apotex Corp. (collectively "Apotex") appeal the judgment of the district court, which dismissed Apotex's declaratory judgment action for lack of jurisdiction. *Torpharm, Inc. v. Pfizer, Inc.*, No. 03-CV-990, 2004 WL 1465756 (D.Del. June 28, 2004). Because Apotex's appeal is moot, we *vacate* and *remand* with instructions to *dismiss.*

Less than one week before oral argument, Pfizer covenanted not to sue Apotex for infringement of U.S. Patent No. 4,743,450. A covenant not to sue, such as that provided by Pfizer, moots an action for declaratory judgment. *SeeAmana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed.Cir.1999) ("[A] covenant not to sue ... is sufficient to divest a trial court of jurisdiction over a declaratory judgment action."). As a result, the judgment and opinion of the district court are vacated and the case is remanded with instructions to dismiss for lack of jurisdiction. *SeeU.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 23, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994) ("[V]acatur must be granted where mootness results from the unilateral action of the party who prevailed in the lower court."); *Najjar v. Ashcroft*, 273 F.3d 1330, 1340 (11th Cir.2001); *Mayfield v. Dalton*, 109 F.3d 1423, 1427 (9th Cir.1997).

COSTS

Apotex shall have its costs.

C.A.Fed.,2005.
Apotex Inc. v. Pfizer, Inc.
125 Fed.Appx. 987, 2005 WL 821393 (C.A.Fed.)

END OF DOCUMENT

EXHIBIT 23

U.S. Census Bureau
State & County QuickFacts

Delaware

People QuickFacts	Delaware	USA
Population, 2006 estimate	853,476	299,398,484
Population, percent change, April 1, 2000 to July 1, 2006	8.9%	6.4%
Population, 2000	783,600	281,421,906
Persons under 5 years old, percent, 2006	6.6%	6.8%
Persons under 18 years old, percent, 2006	23.8%	24.6%
Persons 65 years old and over, percent, 2006	13.4%	12.4%
Female persons, percent, 2006	51.5%	50.7%
White persons, percent, 2006 (a)	74.5%	80.1%
Black persons, percent, 2006 (a)	20.9%	12.8%
American Indian and Alaska Native persons, percent, 2006 (a)	0.4%	1.0%
Asian persons, percent, 2006 (a)	2.8%	4.4%
Native Hawaiian and Other Pacific Islander, percent, 2006 (a)	0.1%	0.2%
Persons reporting two or more races, percent, 2006	1.4%	1.6%
Persons of Hispanic or Latino origin, percent, 2006 (b)	6.3%	14.8%
White persons not Hispanic, percent, 2006	69.0%	66.4%
Living in same house in 1995 and 2000, pct 5 yrs old & over	56.0%	54.1%
Foreign born persons, percent, 2000	5.7%	11.1%
Language other than English spoken at home, pct age 5+, 2000	9.5%	17.9%
High school graduates, percent of persons age 25+, 2000	82.6%	80.4%
Bachelor's degree or higher, pct of persons age 25+, 2000	25.0%	24.4%
Persons with a disability, age 5+, 2000	131,794	49,746,248
Mean travel time to work (minutes), workers age 16+, 2000	24.0	25.5
Housing units, 2006	382,828	126,316,181
Homeownership rate, 2000	72.3%	66.2%
Housing units in multi-unit structures, percent, 2000	18.7%	26.4%
Median value of owner-occupied housing units, 2000	$130,400	$119,600
Households, 2000	298,736	105,480,101
Persons per household, 2000	2.54	2.59
Median household income, 2004	$49,545	$44,334
Per capita money income, 1999	$23,305	$21,587
Persons below poverty, percent, 2004	9.6%	12.7%

Business QuickFacts	Delaware	USA
Private nonfarm establishments, 2005	25,319[1]	7,499,702
Private nonfarm employment, 2005	392,840[1]	116,317,003
Private nonfarm employment, percent change 2000-2005	4.1%[1]	2.0%

Nonemployer establishments, 2005	52,314	20,392,068
Total number of firms, 2002	63,570	22,974,655
Black-owned firms, percent, 2002	6.7%	5.2%
American Indian and Alaska Native owned firms, percent, 2002	S	0.9%
Asian-owned firms, percent, 2002	3.0%	4.8%
Native Hawaiian and Other Pacific Islander owned firms, percent, 2002	0.0%	0.1%
Hispanic-owned firms, percent, 2002	1.4%	6.8%
Women-owned firms, percent, 2002	24.1%	28.2%
Manufacturers shipments, 2002 ($1000)	16,417,927	3,916,136,712
Wholesale trade sales, 2002 ($1000)	17,292,794	4,634,755,112
Retail sales, 2002 ($1000)	10,912,971	3,056,421,997
Retail sales per capita, 2002	$13,538	$10,615
Accommodation and foodservices sales, 2002 ($1000)	1,231,595	449,498,718
Building permits, 2006	6,504	1,838,903
Federal spending, 2004 ($1000)	5,253,147[1]	2,143,781,727[2]

Geography QuickFacts	**Delaware**	**USA**
Land area, 2000 (square miles)	1,953.56	3,537,438.44
Persons per square mile, 2000	401.0	79.6
FIPS Code	10	

1: Includes data not distributed by county.
2: Includes data not distributed by state.

(a) Includes persons reporting only one race.
(b) Hispanics may be of any race, so also are included in applicable race categories.

D: Suppressed to avoid disclosure of confidential information
F: Fewer than 100 firms
FN: Footnote on this item for this area in place of data
NA: Not available
S: Suppressed; does not meet publication standards
X: Not applicable
Z: Value greater than zero but less than half unit of measure shown

Source U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, Census of Population and Housing, Small Area Income and Poverty Estimates, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits, Consolidated Federal Funds Report
Last Revised: Wednesday, 02-Jan-2008 15:11:15 EST